

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.)	
a Private Limited Company)	
of the United Kingdom)	
)	
Defendants.		

**DePuy Mitek's Statement of Undisputed Material Facts in Support of its Motion
for Summary Judgment of Infringement and No Inequitable Conduct**

**I. Statement of Undisputed Material Facts in Support of DePuy Mitek's
Summary Judgment of Infringement Memorandum**

Mitek Fact #1

Claim 1 of U.S. Patent No. 5,314,446 Patent ("446 Patent") is:

A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core (Ex. 1 at 8:63-9:9).

Mitek Fact #2

Claim 2 of Mitek's 446 Patent is "[t]he surgical suture of claim 1 wherein the suture is attached to a needle (*id.* at 9:10-11).

Mitek Fact #3

Claim 8 of Mitek's 446 Patent is "[t]he surgical suture of claim 1 wherein the second set of yarns is PET" (*id.* at 10:7-8).

Mitek Fact #4

Claim 9 of Mitek's 446 Patent is "[t]he surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent" (*id.* at 10:9-11).

Mitek Fact #5

Claim 12 of Mitek's 446 Patent is "[t]he surgical suture of claim 8 wherein the suture is attached to a needle" (*id.* at 10:18-19).

Mitek Fact #6

The 446 patent states that "it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid" (*id.* at 2:58-62).

Mitek Fact #7

The 446 patent states that "[s]urprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security" (*id.* at 2:49-66).

Mitek Fact #8

TigerWire is made by Pearsalls and sold by Arthrex (Ex. 2 at ARM18533).

Mitek Fact #9

TigerWire's yarns are identical to FiberWire with the exception that one PET yarn is replaced by one nylon yarn (Ex. 3).

Mitek Fact #10

TigerWire is braided in the same way as FiberWire (Ex. 4 at 31:24–32:2).

Mitek Fact #11

FiberWire and TigerWire are surgical sutures (Ex. 5).

Mitek Fact #12

FiberWire sutures contain a sheath or cover formed by braiding yarns of polyethylene (PE) and yarns of polyethylene terephthalate (“PET”) (Ex. 4 at 43:15-19; Ex. 5).

Mitek Fact #13

Dr. Mukherjee testified that:

Q. Okay. And is the FiberWire heterogeneous braid composed of a first and second set of continuous and discrete yarns?

A. Yes.

Q. Okay. And is the FiberWire heterogeneous sheath braid composed of discrete yarns in a sterilized braided construction?

A. Yes (Ex. 6 at 362:1-8).

Mitek Fact #14

Dr. Mukherjee is Arthrex’s expert who submitted an expert report opining that FiberWire does not infringe the 446 Patent.

Mitek Fact #15

The polyethylene terephthalate yarns in FiberWire and TigerWire are continuous and discrete (*id.* at 362:1-4).

Mitek Fact #16

Mr. Dreyfuss testified that:

Q. What is -- How do you characterize that strand of polyethylene when Pearsalls receives it?

A. It is a various -- various individual filaments make up the yarn that's received. And the yarn may be several filaments to many (Ex. 4 at 50:21-51:1) (objection omitted).

Mitek Fact #17

Mr. Dreyfuss testified that:

Q. Same way? So the PET used in Arthrex's FiberWire sutures is in the form of yarn, and that PET yarn is made up of several twisted monofilaments of PET?

A. Correct (*id.* at 64:14-17).

Mitek Fact #18

Dr. Mukherjee testified that:

Q. And does the FiberWire heterogeneous braided sheath have a braided construction where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set?

A. There is intertwining contact, yes (Ex. 6 at 362:9-14).

Mitek Fact #19

There are no bioabsorbable materials in FiberWire or TigerWire (Ex. 5).

Mitek Fact #20

FiberWire and TigerWire have a coating and both FiberWire and TigerWire have a heterogeneous braid of dissimilar non-bioabsorbable yarns of PE and PET, materials, wherein the PE yarns are in direct intertwining contact with the PET yarns, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid (Ex. 7 at ¶36).

Mitek Fact #21

FiberWire is made from ultra high molecular weight PE ("UHMW PE"), which is a type of PE (Ex. 8 at ¶¶149-157).

Mitek Fact #22

Arthrex documents refer to UHMW PE as simply PE (Ex. 5; Ex. 9 at ARM002188-89; Ex. 10).

Mitek Fact #23

Different FiberWire sizes are braided in the same manner (Ex. 4 at 38:20-24).

Mitek Fact #24

The FiberWire size 4-0 suture has the same sheath configuration as the other size FiberWire sutures (*id.* at 104:17-105:9).

Mitek Fact #25

FiberWire size 4-0 does not have a core (*id.* at 55:21-23).

Mitek Fact #26

Arthrex's FiberWire and TigerWire suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF, AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR-1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (Ex. 2).

Mitek Fact #27

Mr. Grafton testified:

Q. Was the initial prototype 100 percent ultra-high molecular weight polyethylene?

A. For the fourth time, yes (Ex. 11 at 51:15-17).

Mitek Fact #28

Mr. Grafton testified:

Q. Okay. And you said the strength was excellent, I believe, of the initial prototype, but the knot slippage was poor; is that right?

A. Yes.

Q. Okay. When you say the slippage was poor of the initial prototype, what do you mean?

A. Less than the tensile strength capability of the existing Arthrex product (*id.* at 52:5-12).

Mitek Fact #29

Mr. Grafton testified:

Q. Ultra-high molecular weight polyethylene, is that a lubricious material?

A. Yes.

Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?

A. Yes (*id.* at 52:24-53:5).

Mitek Fact #30

Mr. Grafton testified:

Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the prototype; right?

A. Yes.

Q. And your idea was to add the PET and to improve the knot security?

A. I've lost count, it's been so many times, but the answer again is yes (*id.* at 53:20-54:5) (objection omitted).

Mitek Fact #31

Mr. Grafton testified:

Q. And the prototype of PET braided with ultra-high molecular weight polyethylene had good knot security?

A. Yes (*id.* at 54:24-55:1).

Mitek Fact #32

FiberWire does have a coating that acts as a lubricant (Ex. 5).

Mitek Fact #33

Dr. Brookstein stated that FiberWire's coating does not materially affect the basic and novel characteristics of the invention as defined by Mitek (Ex. 7 at ¶36).

Mitek Fact #34

Regardless of the coating, FiberWire still has a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid (*id.* at ¶36).

Mitek Fact #35

FiberWire's coating is non-bioabsorbable (Ex. 5).

Mitek Fact #36

FiberWire's coating does not materially affect the non-bioabsorbability of FiberWire's yarns (Ex. 7 at ¶36).

Mitek Fact #37

FiberWire coating does not materially affect FiberWire from having PE braided in direct intertwining contact with PET (*id.*).

Mitek Fact #38

FiberWire's coating does not materially affect FiberWire's PE and PET yarns from contributing to the overall properties of the heterogeneous braid (*id.*).

Mitek Fact # 39

Mr. Dreyfuss testified:

Q. What is the purpose of the nylon marking strand in Arthrex's TigerWire product?

A. Identification. Visual identification (Ex. 12 at 74:21-23).

Mitek Fact # 40

Dr. Brookstein stated that TigerWire's single nylon strand does not materially affect the basic and novel characteristics as defined by Mitek (Ex. 7 at ¶45).

Mitek Fact # 41

Nylon makes up only about 3.4% of the TigerWire suture (Ex. 3).

Mitek Fact # 42

The inclusion of a nylon yarn instead of one yarn of PET does not materially affect the basic and novel characteristics of the invention because the braid is still a heterogeneous braid of non-bioabsorbable yarns of the type claimed (Ex. 7 at ¶45).

Mitek Fact #43

The inclusion of a nylon yarn instead of one yarn of PET does not materially affect the basic and novel characteristics of the invention because at least one yarn of PE is in direct intertwining contact with a PET yarn (*id.*).

Mitek Fact #44

The inclusion of a nylon yarn instead of one yarn of PET does not materially affect the basic and novel characteristics of the invention because the nylon does not materially affect the yarns from contributing to the properties of the overall braided suture (*id.*).

Mitek Fact #45

Mr. Dreyfuss testified:

Q. Other than the visual distinction that you can see with the introduction of a nylon marking strand, does the nylon marking strand in TigerWire affect any other characteristic of the braided suture?

A. Yes.

Q. What is -- what?

A. Minute differences in its feel and strength, characteristics (Ex. 12 at 75:7-14).

Mitek Fact #46

Dr. Mukherjee testified that:

Q. Okay. And the next part says, "Each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group of PET, nylon and aramid." Do you see that?

A. Yes.

Q. Does FiberWire meet that criteria?

A. It has the PET in it.

Q. So, it meets that criteria?

A. Uh-huh (Ex. 6 at 363:7-16).

Mitek Fact #47

Arthrex's FiberWire sutures have a core except for 4-0 FiberWire (Ex. 3).

Mitek Fact #48

Arthrex's FiberWire needle products have either FiberWire suture attached to a needle (Ex. 2).

Mitek Fact #49

Each FiberWire suture product has PET as a second set of yarns (Ex. 3).

Mitek Fact #50

Every FiberWire and TigerWire construction has a ratio of the cross-sectional area of ultra high molecular weight PE in the sheath and core to the total cross sectional area of all the yarns in the surgical suture that ranges from 20 to 80 percent (Ex. 7 at ¶49; Ex. 3).

Mitek Fact #51

Arthrex, Inc. sells FiberWire and TigerWire in the United States (Ex. 13).

Mitek Fact #52

Arthrex's FiberWire and TigerWire needle products includes all Arthrex's products that are sold with a needle attached to a FiberWire or TigerWire suture including at least the following Arthrex catalog product codes AR-7200, AR-7202, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7211, AR-7219, AR-7220, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1324BNF, AR-1920BNP, AR-1934BNF, AR-1920BN, AR-1920BNF, AR-1925BNF, AR-1925BNP, AR-1927BNF, AR-1928SNF, and AR-1928SNF-2 (Ex. 2).

II. Statement of Undisputed Material Facts in Support of DePuy Mitek's Summary Judgment of No Inequitable Conduct Memorandum

Mitek Fact #53

The application that matured into U.S. Patent No. 5,134,446 (the 511 application) was filed on February 19, 1992 (Ex. 1).

Mitek Fact #54

Dr. Mark Steckel is named as a co-inventor of the 511 application (Ex. 1).

Mitek Fact #55

The 511 application as originally filed had 24 claims (*id.* at DMI 000033-36).

Mitek Fact #56

Originally filed claims 1-20 ("braid claims") of the 511 application are drawn to a heterogeneous braid (*id.* at DMI000033-35 and 187).

Mitek Fact #57

Originally filed claims 21-24 ("suture claims") of the 511 application are drawn to a surgical suture (*id.* at DMI000035 and 187).

Mitek Fact #58

Messrs. Matthew Goodwin and Hal Woodrow are two in-house attorneys from Johnson & Johnson (Ex. 14 at 7:9-21, 8:4-10; Ex. 15 at 6:25-7:4).

Mitek Fact #59

Messrs. Matthew Goodwin and Hal Woodrow prosecuted the 511 application (Ex. at 16 at DMI000014, 15, 64, 197, 250, and 261).

Mitek Fact #60

On February 19, 1992, the day the 511 application was filed, Mr. Goodwin submitted an Information Disclosure Statement for the 511 application (*id.* at DMI000010 and 63-64).

Mitek Fact #61

Mr. Goodwin disclosed eleven references including U.K. Patent Application GB 2 218 321A (“Burgess”) in the information disclosure statement dated February 19, 1992 (*id.* at DMI000063-64 and 185).

Mitek Fact #62

During the prosecution of the 511 application, the first office action issued on July 8, 1992 (*id.* at DMI000186).

Mitek Fact #63

In the first office action, the U.S. Patent & Trademark Office (“Patent Office”) issued a restriction (*id.* at DMI000187-188).

Mitek Fact #64

The first office action states that claims 1-20 were useful as a fishing line (*id.* at DMI000187).

Mitek Fact #65

The first office action states that the invention of claims 1-20 are patentably distinct from the invention of claims 21-24 (*id.* at DMI000187-88).

Mitek Fact #66

The first office action states that the inventions of the braid and suture claims “have acquired a separate status in the art because of their recognized divergent subject matter” (*id.* at DMI000188).

Mitek Fact #67

Applicants elected to prosecute the “suture” claims (*id.*).

Mitek Fact #68

The Examiner stated that there is nothing in the record to show the braid claims and suture claims are obvious variants (Ex. 16 at DMI000187).

Mitek Fact #69

In the first office action, the Patent Office rejected the suture claims as obvious or not patentably distinct over U.K. Patent Application 2,218,312A, (Burgess) (*id.* at DMI000189).

Mitek Fact #70

U.K. Patent Application 2,218,312A, (Burgess) discloses a fishing line (*id.* at DMI000122-125).

Mitek Fact #71

In the first office action response, Mr. Goodwin confirmed the prior election to prosecute the sutures claims without traverse (*id.*).

Mitek Fact #72

In the first office action response, Mr. Goodwin traversed the Examiner’s rejection of the suture claims over the Burgess fishing line reference (*id.*).

Mitek Fact #73

In the first office action response, Mr. Goodwin argued that Burgess was nonanalogous art (*id.* at DMI 000194-197).

Mitek Fact #74

In the first office action response, Mr. Goodwin argued that persons wanting to make a suture would not look to the fishing line art as instructive (*id.*).

Mitek Fact #75

In the first office action response, Mr. Goodwin argued that some of the property considerations for fishing lines, such as disclosed in Burgess, are different from some of the property considerations for surgical sutures (*id.*).

Mitek Fact #76

In the first office action response, Mr. Goodwin pointed out that an important characteristic of sutures –which holds wounds together– is knot strength (*id.* at DMI 000195).

Mitek Fact #77

Burgess does not mention knot strength (*id.* at DMI000122-125).

Mitek Fact #78

In the first office action response, Mr. Goodwin explained that sutures and fishing line have different requirements because a surgeon ties sutures into conventional square knots at a very fast pace for patient safety (*id.* at DMI000196).

Mitek Fact #79

In the first office action response, Mr. Goodwin explained that sutures and fishing line have different requirements because surgeons generally form a pre-knot with a suture and then slide it down the suture until the knot is adjacent to the body tissue desired to be stitched (*id.*).

Mitek Fact #80

In the first office action response, Mr. Goodwin explained that sutures and fishing line have different requirements because after a suture knot is placed, surgeons make additional throws that can be added for knot security (*id.*).

Mitek Fact #81

In the first office action response, Mr. Goodwin noted that the Burgess fishing line had some filaments composed of high tensile polythene thread which, although having some good strength properties, has poor knot strength properties (*id.* at DMI000195-196).

Mitek Fact #82

In the first office action response, Mr. Goodwin explained the dissimilarities in property requirements for sutures versus fishing lines (*id.*).

Mitek Fact #83

In the first office action response, Mr. Goodwin stated “[i]n view of the dissimilarities in property requirements between sutures and fishing line, there would simply be no incentive for a medical designer who wishes to improve the properties of braided sutures to study the art related to braided fishing lines. Even if he did use the teachings of the fishing line art to modify a suture, then he would inevitably design an unacceptable suture” (*id.* at DMI000196-197).

Mitek Fact #84

After receiving the first office action response, the Examiner issued a second office action (“the second office action”) during the prosecution of the 511 application (*id.* at DMI000201-205).

Mitek Fact #85

The second office action states that the rejection over Burgess was moot (*id.* at DMI000204).

Mitek Fact #86

After the second office action, there was no further discussion of Burgess during the prosecution of the 511 application (*id.*).

Mitek Fact #87

In the second office action, the Examiner rejected the suture claims over two different patents including U.S. Patent No. 5,147,400 (*id.* at DMI000202-203; 215-228).

Mitek Fact #88

The second office action states that Kaplan disclosed a core and a braided sheath component made from “individual filaments having more than two different chemical compositions, one or more of which optionally being nonbioabsorbable” (*id.* at DMI000203).

Mitek Fact #89

Mr. Goodwin submitted a response to the second office action stating that the claimed inventions were distinguishable from Kaplan because Kaplan failed to disclose the claimed braid of direct intertwining contact (*id.* at DMI000239-244).

Mitek Fact #90

The Patent Office issued a third office action on March 18, 1993 during the prosecution of the 511 application (“third office action”) (*id.* at DMI000246).

Mitek Fact #91

In the third office action, the Patent Office rejected the suture claims based at least in part on Kaplan (*id.* at DMI000247).

Mitek Fact #92

The third office action states that the Applicant's arguments in response to the second office action "are deemed moot in view of the new grounds of rejection" (*id.* at DMI000248).

Mitek Fact #93

The third office action states that Kaplan disclosed a braided sheath component that may be fabricated from individual filaments having more than two different chemical compositions, one or more of which optionally being nonbioabsorbable (*id.* at DMI000241-248).

Mitek Fact #94

On August 3, 1993, Mr. Woodrow submitted a response to the third office action ("third office action response") (*id.* at DMI000258).

Mitek Fact #95

In the third office action response, applicants amended the claims to exclude biomaterials as the first and second fiber-forming materials (*id.* at DMI000259).

Mitek Fact #96

In the third office action response, applicants argued that the claims were patentable over Kaplan (*id.* at DMI000259-261).

Mitek Fact #97

In the third office action response, Mr. Woodrow explained, *inter alia*, that Kaplan did not anticipate or render obvious the amended claimed invention because Kaplan disclosed sheath yarn components that are "bioabsorbable or semi-bioabsorbable" (*id.* at DMI000259), and the amended claims recited nonbioabsorbable yarns (*id.*).

Mitek Fact #98

After the third office action response was submitted, the Patent Office issued a Notice of Allowance for the 511 application (*id.* at DMI000266).

Mitek Fact #99

Arthrex does not allege that any material information was withheld with respect to Kaplan (Ex. 17 at ¶¶18-21; Ex. 19).

Mitek Fact #100

Arthrex alleges that inequitable conduct was committed with respect to Kaplan because the 511 patent applicants and their attorneys mischaracterized and misrepresented Kaplan (Ex. 17 at ¶19).

Mitek Fact #101

Arthrex's allegations of inequitable conduct regarding Burgess are based on Mr. John Witherspoon's opinions (Ex. 20 at ¶¶58-63; Ex. 21 at ¶¶ 5-9).

Mitek Fact #102

Mr. Witherspoon opined that the following three statements in the response to the rejection over Burgess were affirmative misrepresentations:

- In fact, the fishing line of Burgess would have poor knot strength properties because of its braided construction;
- The property requirements for fishing line yield a braid with poor knot strength and security, and the requirements for sutures yield a braid which has by necessity excellent knot strength and security; and
- Even if [a medical designer] did use the teachings of the fishing line art to modify a suture then he would inevitably design an unacceptable suture (Ex. 21. at ¶7).

Mitek Fact #103

Mr. Witherspoon states that the three statements of fact 105 are material misrepresentations because Dr. Steckel allegedly testified that he "believed that a braided structure of Dyneema [a tradename for a type of polyethylene] and PET (a polyester) could have good knot characteristics" (*id.* at ¶¶6, 8 *citing* Dr. Steckel at 188:13-192:9).

Mitek Fact #104

Kaplan was discussed in two office actions and two responses during the prosecution of the 511 application (Ex. 16 at DMI000201-205; 235-242; 246-249; 258-263).

Mitek Fact #105

Kaplan was not withheld during the prosecution of the 511 application (*id.*).

Mitek Fact #106

The Patent Examiner considered Kaplan during the prosecution of the 511 application (*id.*).

Mitek Fact #107

Arthrex alleges that the 511 patent applicants and their attorneys falsely represented that Kaplan's sheath yarn component "always contains at least in part, a bio-absorbable portion and that Kaplan teaches away from a combination of non-bioabsorbable yarns" (*id.*).

Mitek Fact #108

Mr. Woodrow testified that:

Q. What was Ethicon's belief as to what Kaplan taught regarding the materials on the sheath of Kaplan?

A. That the sheath yarn is a biocompatible -- the sheath yarn is biocompatible and it is bioabsorbable or semibioabsorbable (Ex. 15 at 157:8-13).

Mitek Fact #109

Neither Dr. Gitis nor Dr. Mukherjee offered any opinions regarding Kaplan's teachings.

Mitek Fact #110

Mr. Witherspoon did not opine on any misconduct regarding Kaplan (Ex. 20 and 21).

Mitek Fact #111

Arthrex failed to plead any evidence of intent with respect to Kaplan in its answers (Ex. 17; Ex. 18).

Mitek Fact #112

Arthrex did not to identify any evidence of intent to deceive with respect to Kaplan in response to Mitek's interrogatories (Ex. 19).

Mitek Fact #113

Arthrex did not supplement its response to Mitek's interrogatory no. 6 after Arthrex deposed the prosecuting attorneys, Mr. Goodwin and Mr. Woodrow, and co-inventor Dr. Steckel.

Mitek Fact #114

Arthrex has no evidence that Mr. Woodrow thought Kaplan disclosed something different than what Mr. Woodrow explained to the Patent Office (Exs. 17, 18 and 19).

Mitek Fact #115

Dr. Steckel's testimony cited by Mr. Witherspoon in his rebuttal report was about his work developing *sutures* and what would make "an acceptable *suture*," not *fishing lines* (Ex. 21 at ¶6, citing Dr. Steckel at 188:13-192:9; Ex. 22 at 138:21-139:21).

Mitek Fact #116

There is no evidence that Dr. Steckel was familiar with fishing line properties.

Mitek Fact #117

There is no evidence that Dr. Steckel considered designing sutures from fishing lines.

Mitek Fact #118

There is no evidence that Dr. Steckel disagreed with Mr. Goodwin's argument that Burgess was nonanalogous art.

Mitek Fact #119

Mr. Witherspoon states in his March 3, 2006 report that: "If the term "PE" in the asserted claims of the '446 patent is construed by the court to include UHMWPE, then I would expect to testify that Dr. Steckel, and Mr. Hunter, and/or Mr. Goodwin may have violated their duty to disclose material information to the PTO, as required by Rule 56" (Ex. 20 at ¶58).

Mitek Fact #120

At his deposition, Mr. Witherspoon testified that:

Q. In paragraph 58 of your first report, you begin a discussion that proceeds for several paragraphs about whether Dr. Steckel, Mr. Hunter and/or Mr. Goodwin may have violated their duty to disclose material information to the Patent Office.

And I note that in that first sentence in paragraph 58, you say that "you expect to testify that these gentlemen may have violated their duty to disclose material information to the PTO." And I note the language may have violated. Do you intend to testify that they did violate their duty to disclose material, or that they may have violated their duty to disclose material information?

A. Well, I don't know quite how to answer

that, other than that it depends upon how the evidence at trial comes to -- comes in. And I say that because there's some additional information that I think needs to be found, for which I don't have access now, that would bear on whether there was a violation or not. And that turns on answers to the question of who knew what when. At this point in time, there's some circumstantial evidence that suggests that Mr. Steckel was aware of what the patent examiner had been told, but I can't point to a particular document or a piece of testimony that clearly establishes that. That's the reason for the use of the word may. In other words, there's a lot of information that indicates to me that there may have been a violation here, and this isn't just pulled out of thin air. But at this point in time, I could not specifically say what Dr. Steckel knew when, or what Mr. Goodwin knew when, or Mr. Hunter knew when. But there's evidence from which one could infer that they knew.

Q. And without evidence, without knowledge of what they knew, you cannot conclude that any of those gentlemen violated their duty of disclosure?

THE WITNESS: Could you read that back, please?

Q. And without knowledge of what those gentlemen knew, and when they knew it, you cannot conclude that any of them violated their duty of disclosure?

THE WITNESS: Well, no, I stand by the statement that I've made here, that they may have violated their duty. And I have referred to the deposition testimony of Dr. Steckel and Mr. Goodwin. But I would be -- I would not be inclined, at this point, to say that they, in fact, did violate it, knowing only what I know now (Ex. 22. at 184:7-186:18) (objections omitted).

Mitek Fact #121

Arthrex did not plead any evidence of intent to deceive with respect to Burgess (Ex. 17 at ¶¶18-21).

Mitek Fact #122

Arthrex did not identify any evidence of intent to deceive regarding Burgess in response to Mitek's interrogatory no. 6 (Ex. 19).

Mitek Fact #123

After Arthrex deposed Mr. Goodwin, Mr. Woodrow, and Dr. Steckel, Arthrex did not supplement its response to Mitek's interrogatory no. 6. interrogatory responses and identify any evidence of intent to deceive.

Mitek Fact #124

Dr. Steckel testified that:

A. Well, the patent describes generic classes of polymers, and the high strength aspect of it has more to do with how those polymers were processed. So, any of those polymers that are listed, you know, could be processed in a high strength form or a medium-strength form or a low-strength form.

Q. When you're saying, "these," which one are you talking about?

A. I'm referring to the polymers listed in the claims.

Q. All of them?

A. All of those can be processed to get a range of low, medium, or relatively high strength (Ex. 23 at 106:12-24).

Mitek Fact #125

U.S. Patent No. 5,314,446 discloses a suture having PE braided with PET in direct intertwining contact (Ex. 1 at 3:40-48; 4:30-40).

Mitek Fact #126

Dr. Steckel conceived of the idea of a suture having a braided sheath of ultra-high molecular weight PE and PET in direct intertwining contact before 1992.

Mitek Fact #127

Mr. Witherspoon testified at his deposition that:

Q. Do you plan to testify that material information was withheld from the examiner?

A. Well, you know, obviously, I don't know what questions I'll be asked. But if asked, I would so testify.

Q. And what material information would you testify was withheld from the examiner?

THE WITNESS: That Dr. Steckel and – at least Dr. Steckel, and perhaps Mr. Hunter as well, believed back in 1988 or '89 that a braid made of Spectra, an ultra high molecular weight polyethylene and polyethylene terephthalate, PET, could provide a successful suture, could provide a braid which could be converted into a successful suture.

Q. And it's your opinion that that was a material bit of information for the examiner?

A. Yes, because contrary information was being told to the examiner. Absent the contrary information, then I would not consider this information to be material. But it's material because it is inconsistent with what had been told to the examiner (Ex. 22 at 138:21-139:21) (objections omitted).

Dated: August 11, 2006

Respectfully submitted,

DEPUY MITEK, INC.,

By its attorneys,

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US005314446A

United States Patent [19]

Hunter et al.

[11] Patent Number: **5,314,446**[45] Date of Patent: **May 24, 1994**[54] **STERILIZED HETEROGENEOUS BRAIDS**[75] Inventors: **Alastair W. Hunter, Bridgewater;**
Arthur Taylor, Jr., Plainfield, both of
N.J.; Mark Steckel, Maineville, Ohio[73] Assignee: **Ethicon, Inc., Somerville, N.J.**[21] Appl. No.: **838,511**[22] Filed: **Feb. 19, 1992**[51] Int. Cl.⁵ **D04C 1/00**[52] U.S. Cl. **606/231; 606/228;**
87/7; 87/9; 428/370[58] Field of Search **606/228, 230, 231;**
87/7, 8, 9; 428/225[56] **References Cited****U.S. PATENT DOCUMENTS**

3,187,752	6/1965	Glick	128/335.5
3,463,158	8/1969	Schmitt et al.	606/228
3,527,650	9/1970	Block	117/7
3,636,956	1/1972	Schneider	128/335.5
3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
4,047,533	8/1977	Perciaccante et al.	128/335.5
4,052,988	10/1977	Doddi et al.	128/335.5
4,141,087	2/1979	Shalaby et al.	3/1
4,470,941	9/1984	Kurtz	264/136

4,624,256	11/1986	Messier et al.	128/335.5
4,946,467	8/1990	Ohi et al.	606/228
4,959,069	9/1990	Brennan et al.	606/228
4,979,956	12/1990	Silverstrini	623/13
5,116,360	5/1992	Pinchuk et al.	623/1
5,147,400	9/1992	Kaplan et al.	623/13

FOREIGN PATENT DOCUMENTS

2949920	3/1981	Fed. Rep. of Germany	A61F 1/00
WO86/00020	1/1986	PCT Int'l Appl.	A61L 17/00
2082213	8/1980	United Kingdom	
2218312A	11/1989	United Kingdom	A01K 91/00

Primary Examiner—George F. Lesmes*Assistant Examiner*—Chris Raimund*Attorney, Agent, or Firm*—Hal Brent Woodrow[57] **ABSTRACT**

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

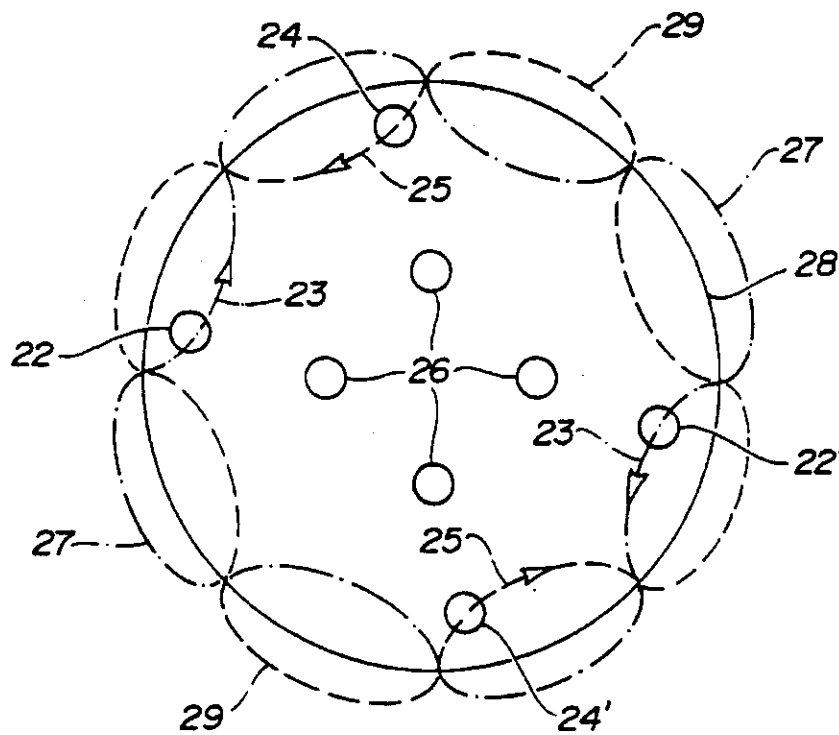
U.S. Patent

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FIG-1



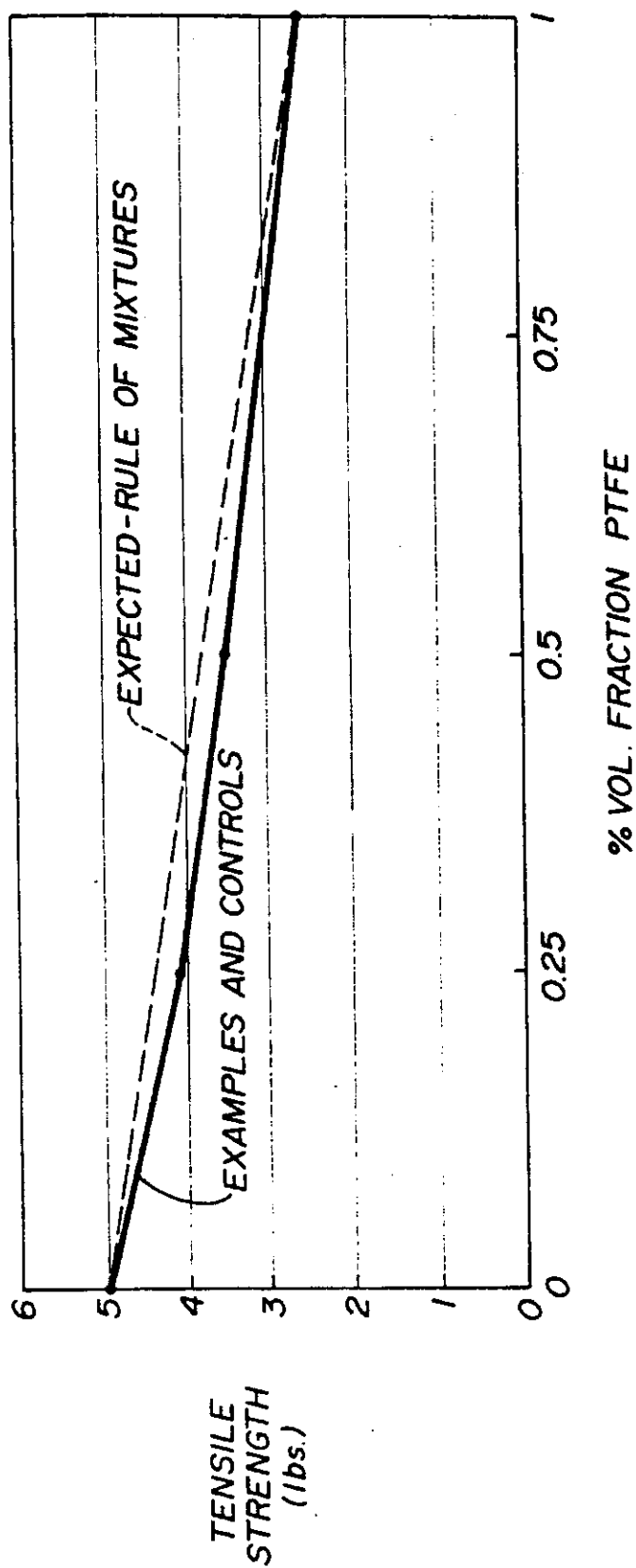
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FIG-2



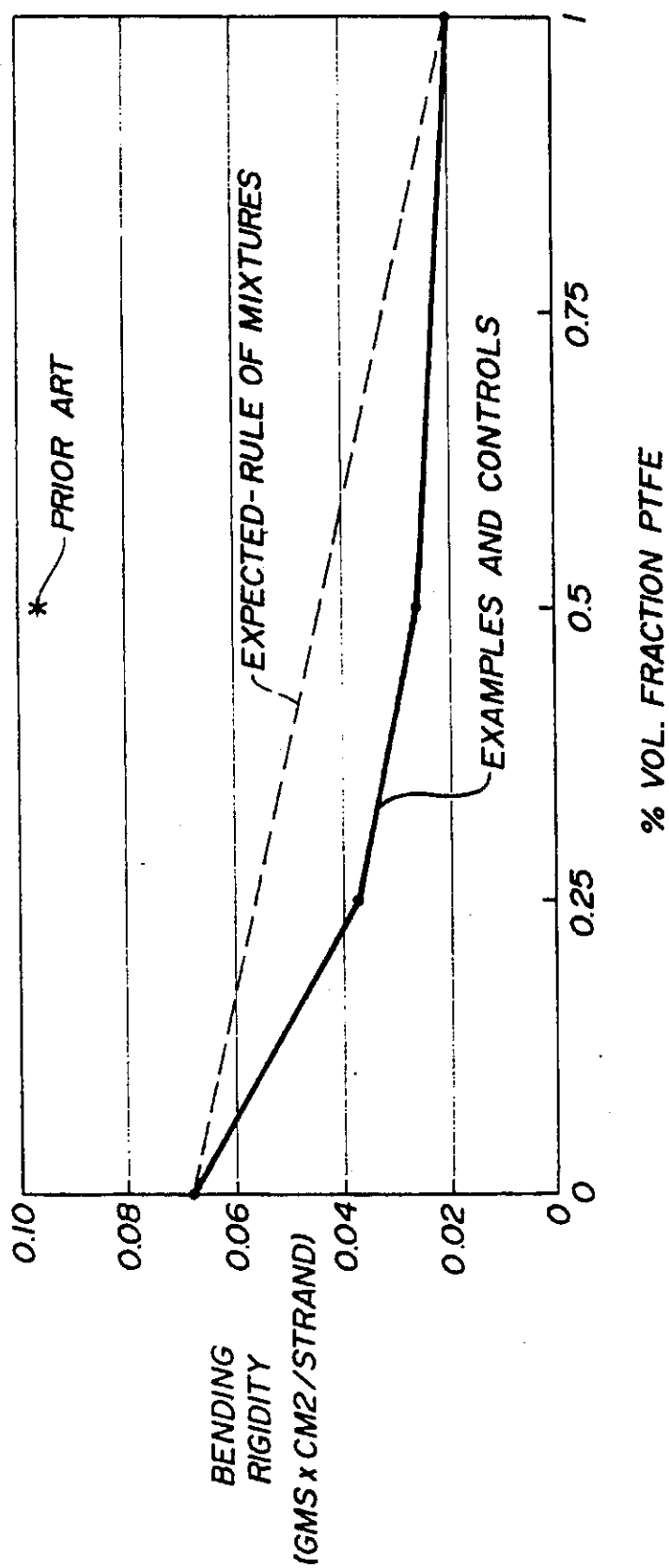
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FIG-3



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STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutylate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ -caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below),

apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricious polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

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the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone,

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ϵ -caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluoroethylene copolymers (PETFE), the polychlorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

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24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves

braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, then the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tying a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tying knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

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CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm ²)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	3
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

As may be expected, the tensile strengths of the heterogeneous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c = (V_f a) (P_a) + (V_f b) (P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and $V_f a$ and $V_f b$ are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the bending moment-radius of curvature plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

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- a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and
 - b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and
 - c) optionally a core.
2. The surgical suture of claim 1 wherein the suture is attached to a needle.
 3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.
 4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.
 5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

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6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.
7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.
8. The surgical suture of claim 1 wherein the second set of yarns is PET.
9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.
10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.
11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.
12. The surgical suture of claim 8 wherein the suture is attached to a needle.

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Arthrex[®]

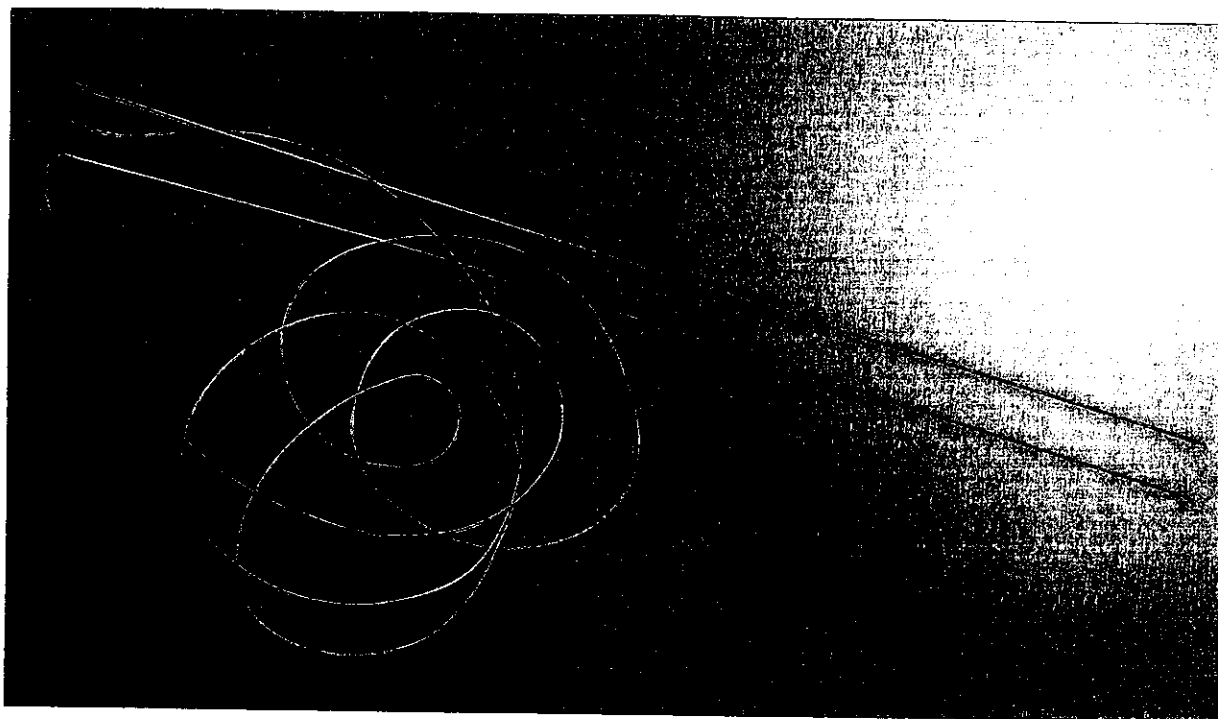
PRODUCT CATALOG

DEPUY MITEK
EXHIBIT 101
04cv12457

ARM 18334



2-0 FiberWire® Meniscus Repair Needles



Key Words: Inside/out meniscus repair, 2-0 FiberWire, superior strength, smooth tie ability, lower knot profile, Joystick instrumentation

The 2-0 FiberWire Meniscus Repair Needles are made of a standard length stainless steel with a 38 inch length of 2-0 FiberWire swedged onto the back end of each needle. This allows the surgeon to perform a standard inside/out meniscus repair with all the benefits of FiberWire's superior strength, feel, abrasion resistance, smooth tie ability and lower knot profile. FiberWire virtually eliminates suture breakage during knot tying and tensioning.

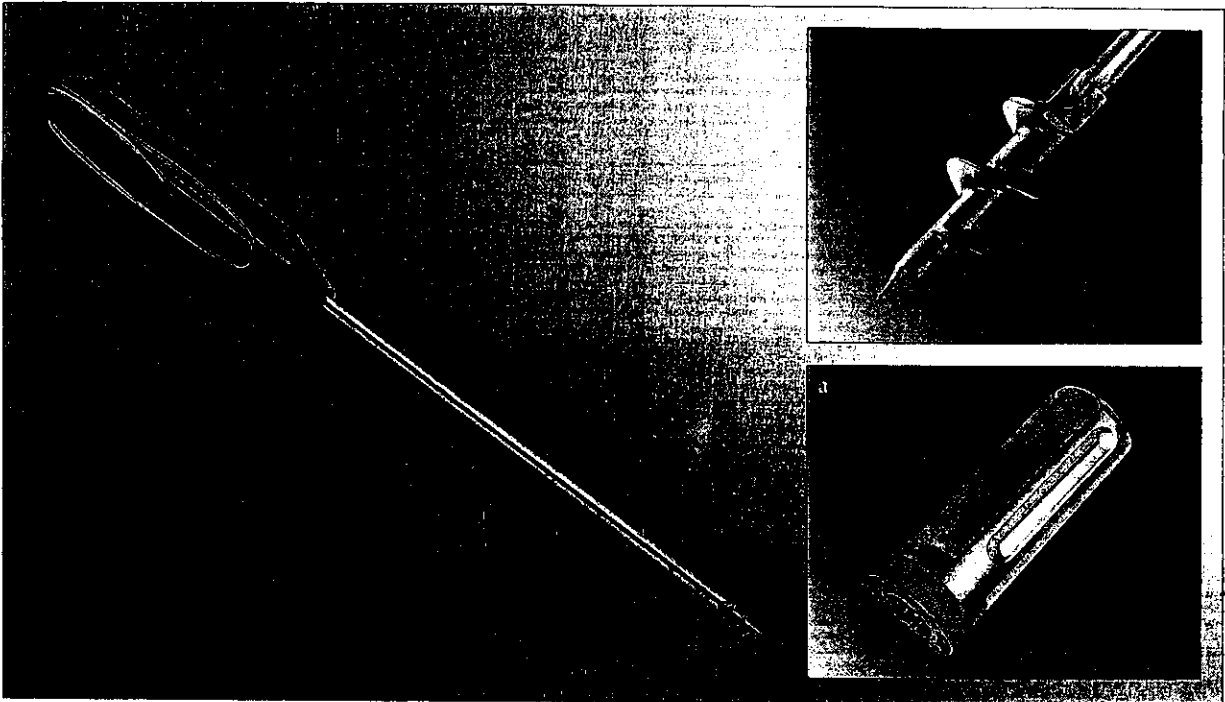
These sterile meniscus repair needles and suture may be used in conjunction with the Meniscal Repair Joystick System to position optimum vertical or horizontal mattress sutures on superior or inferior meniscal surfaces. The meniscal needles also work with other meniscal repair systems.

2-0 FiberWire Meniscus Repair Needles, 2 ea., sterile, SU

AR-7223



Corkscrew™ Suture Anchor



Key Words: Rotator cuff repair, two sutures, cancellous threads, maximum pull-out strength in soft bone, optional attachable handle, FiberWire or TigerTail option

The Corkscrew Suture Anchor is available in 3.5 mm, 5 mm and 6.5 mm diameters that incorporate a small minor diameter and a cancellous screw thread design for maximum pull-out strength in bone. The vertical laser mark on the distal part of the insertion shaft indicates the orientation of the suture eyelets. When the anchor is inserted, the vertical laser mark should point toward the cuff tendon to ensure the suture slides smoothly through the tissue and eyelet minimizing suture abrasion and sliding resistance. The sharp, conical tip ensures that positioning on bone and ease of starting will be accomplished with little effort. The Corkscrew anchor can be inserted through a small stab incision without the need for a cannula. All Corkscrews are supplied sterile and preloaded on a disposable handled inserter with either #2 FiberWire suture or #2 Tevdek suture.

A Corkscrew Starter Awl is available should the surgeon encounter very hard bone and subsequent difficulties starting the anchor in indications other than the humeral head. This Awl requires a handle such as the Tear Drop Handle (AR-2001) or the Ratcheting Screwdriver Handle (AR-1999). A Reusable Corkscrew Handle is available for surgeons who prefer a larger handle design. All implants are sterile and *SU*.

Corkscrew Suture Anchor, 3.5 mm x 12 mm, w/handled inserter and #2 braided suture, qty. 5	AR-1915S
Corkscrew Suture Anchor, 3.5 mm x 12 mm, w/handled inserter and #2 FiberWire, qty. 5	AR-1915SF
Corkscrew Suture Anchor w/Needles, 3.5 mm x 12 mm, w/handled inserter and two size 0 FiberWire (1 blue, 1 white) (driver length for foot and ankle procedures only)	AR-1915SNF
Corkscrew Suture Anchor, 5 mm x 15.5 mm, w/handled inserter and two #2 braided sutures, qty. 5	AR-1920S
Corkscrew Suture Anchor, 5 mm x 15.5 mm, w/handled inserter and two #2 FiberWire, qty. 5	AR-1920SF
Corkscrew Suture Anchor w/Needles, 5 mm x 15.5 mm, w/handled inserter and two #2 FiberWire, qty. 5 (driver length for foot and ankle procedures only)	AR-1920SNF
Corkscrew Suture Anchor, 5 mm x 15.5 mm, w/handled inserter and two #2 TigerTail, qty. 5	AR-1920SFT
Corkscrew Suture Anchor, 6.5 mm x 15.5 mm, w/handled inserter and two #2 braided sutures, qty. 5	AR-1925S
Corkscrew Suture Anchor, 6.5 mm x 15.5 mm, w/handled inserter and two #2 FiberWire, qty. 5	AR-1925SF
Corkscrew Suture Anchor w/Needles, 5 mm x 15.5 mm, w/handled inserter and two #2 FiberWire, qty. 5	AR-1920NSF

U.S. PATENT NOS. 6,117,162; 6,214,031; 6,511,499 and 6,652,563

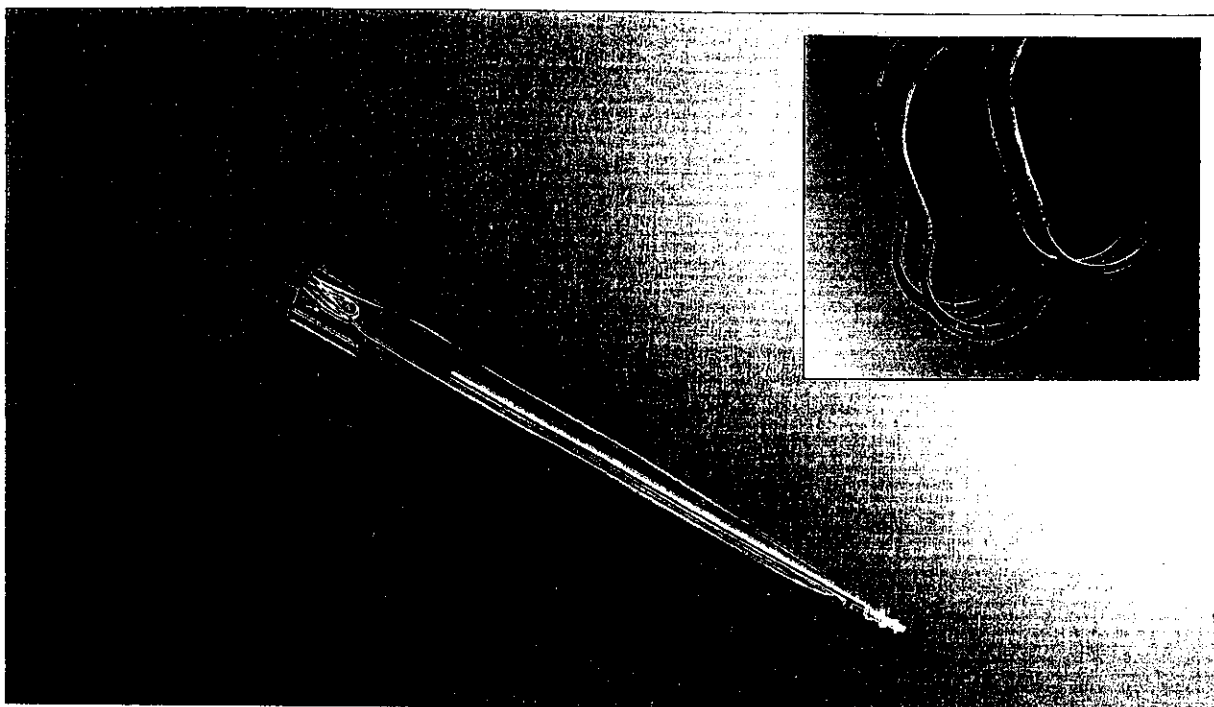
Accessories:

Reusable Corkscrew Handle (a)	AR-1927
Corkscrew Starter Awl, 3.5 mm/5 mm	AR-1915T

Actual Size of 5.0 mm



Bio-Corkscrew™ Suture Anchor w/Needles



Key Words: PLLA material, unique suture eyelet, reduced suture abrasion, maximum pull-out in cancellous bone, ideal for rotator cuff repair

The Bio-Corkscrews with needles are also available for use when performing mini-open rotator cuff procedures. Each end of the suture comes with a 26 mm 1/2 circle, tapered cutting needle swedged-on and housed in a 'trap door' on the inserter handle.

The punch is used to create a pilot hole before the implant is inserted. In hard bone, the tap or combo punch/tap are needed.
The 6.5 mm implant should only be used in soft bone.

Bio-Corkscrew Suture Anchor w/Needles, 5 mm x 17.9 mm, w/handled inserter and two #2 braided sutures (1 green/1 white), sterile, qty. 5, *SU*

AR-1920BN

Bio-Corkscrew Suture Anchor w/Needles, 5 mm x 17.9 mm, w/handled inserter and two #2 FiberWire, sterile, qty. 5, *SU*

AR-1920BNF

Bio-Corkscrew Suture Anchor w/Needles, 6.5 mm x 17.9 mm, w/handled inserter and two #2 braided suture (1 green/1 white), sterile, qty. 5, *SU*

AR-1925BN

Bio-Corkscrew Suture Anchor w/Needles, 6.5 mm x 17.9 mm, w/handled inserter and two #2 FiberWire, sterile, qty. 5, *SU*

AR-1925BNF

Accessory Instrumentation:

Bio-Corkscrew Cutting Punch, 5 mm

AR-1920CPB

Bio-Corkscrew Combo Punch/Tap, 5 mm

AR-1920PTB

Bio-Corkscrew Combo Punch/Tap, 6.5 mm

AR-1925PTB


Bio-Corkscrew Punch, 5 mm

AR-1920PB

Bio-FASTak/Bio-Corkscrew Instrumentation Case

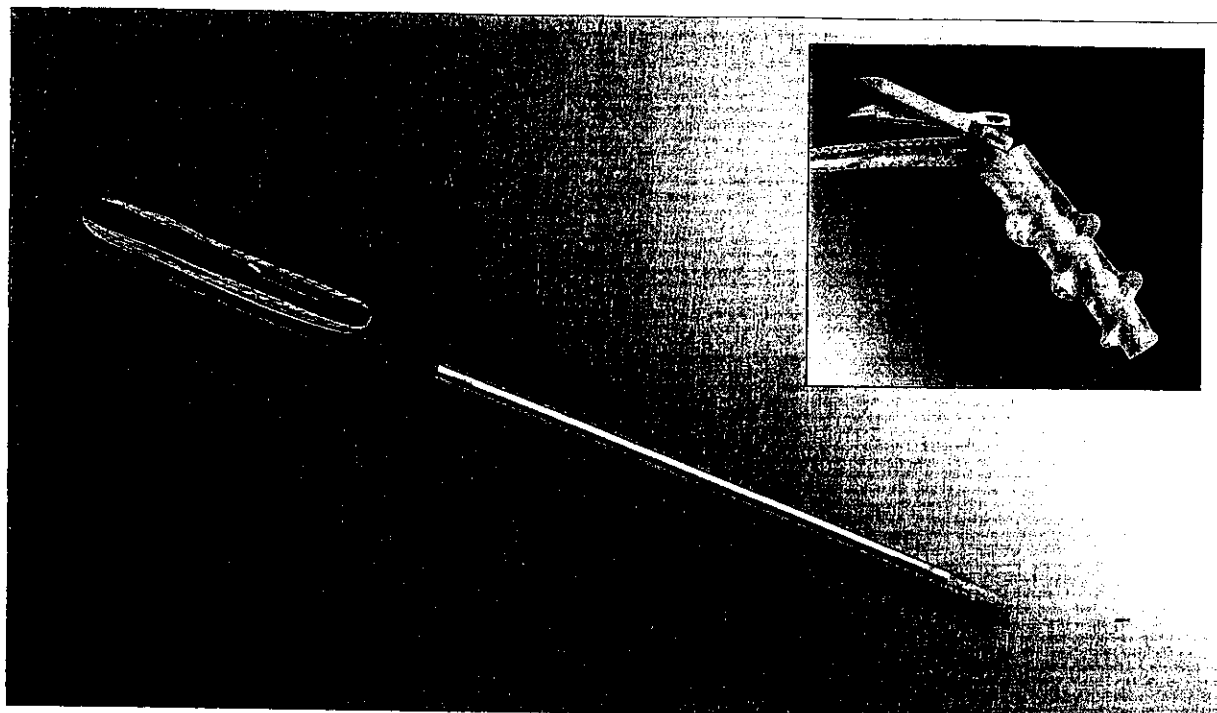
AR-1327

U.S. PATENT NOS. 5,964,783; 6,716,234 and PATENT PENDING

Actual Size of 5 mm 



Bio-Corkscrew™ Suture Anchor w/NeedlePunch Needles



Key Words: PLLA material, unique suture eyelet, reduced suture abrasion, maximum pull-out in cancellous bone, ideal for rotator cuff repair

The Bio-Corkscrews with NeedlePunch Needles are ideal for arthroscopic suture passing using the NeedlePunch instrument. The NeedlePunch Needles are preloaded on one end of each suture and housed inside the driver shaft. As the anchor is being inserted, ensure the laser line is adjacent to the tissue before removing the handle to ensure suture 'slide ability' for easy suture passing and knot tying.

The punch is used to create a pilot hole before the implant is inserted. In hard bone, the tap or punch/tap combo are needed.
The 6.5 mm implant should only be used in soft bone.

Bio-Corkscrew Suture Anchor w/NeedlePunch Needles, 5 mm x 17.9 mm,
w/handled inserter and two #2 FiberWire, sterile, qty. 5, SU
Bio-Corkscrew Suture Anchor w/NeedlePunch Needles, 6.5 mm x 17.9 mm,
w/handled inserter and two #2 FiberWire, sterile, qty. 5, SU

AR-1920BNP

AR-1925BNP

Accessory Instrumentation:

Bio-Corkscrew Cutting Punch, 5 mm
Bio-Corkscrew Combo Punch/Tap, 5 mm
Bio-Corkscrew Combo Punch/Tap, 6.5 mm
Bio-Corkscrew Punch, 5 mm

AR-1920CPB

AR-1920PTB

AR-1925PTB

AR-1920PB

Bio-FASTak/Bio-Corkscrew Instrumentation Case

AR-1327

U.S. PATENT NOS. 5,964,783; 6,716,234 and PATENTS PENDING

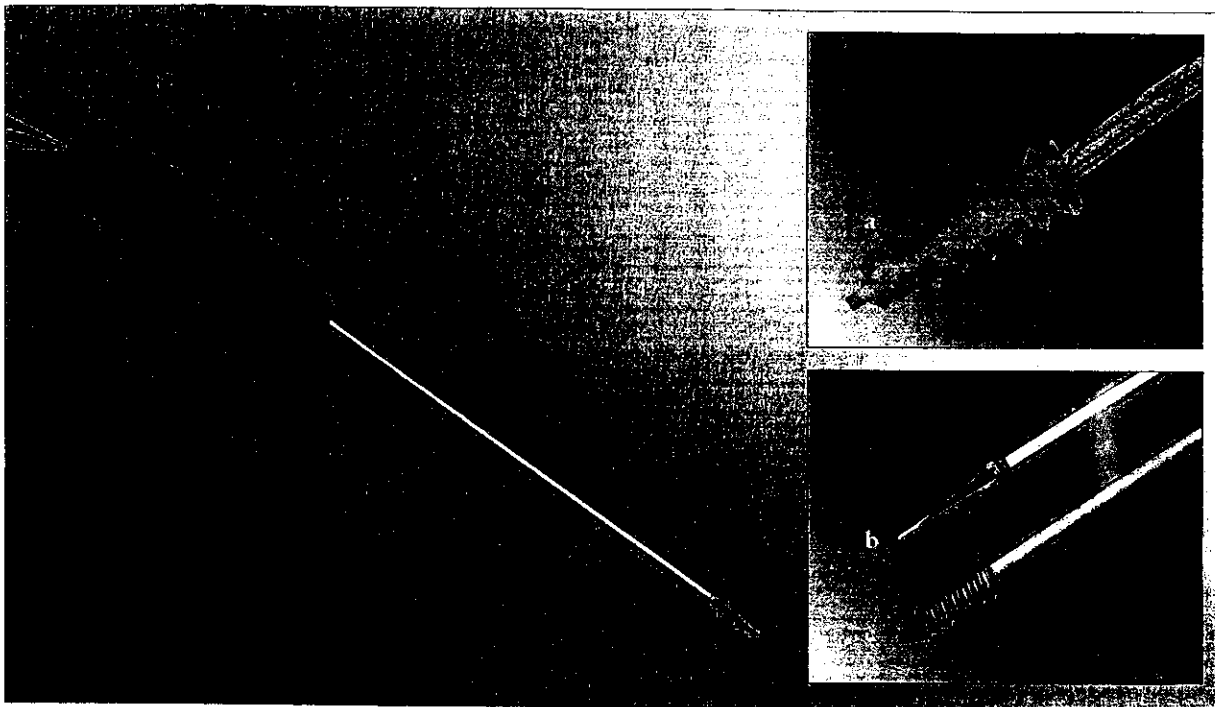
Actual Size of 5 mm

Shoulder Arthroscopy & Mini-Open Repairs 9-7

ARM 18480



Bio-Corkscrew™ FT Suture Anchor



Key Words: PLLA, rotator cuff repair, bioabsorbable suture anchor, internal FiberWire eyelet, full thread purchase of cortical bone increases strength and eliminates anchor “pull back”

The Bio-Corkscrew FT (fully threaded) is a 5.5 mm diameter bioabsorbable suture anchor designed to be inserted flush with the cortical bone surface to maximize fixation strength and anchor stability. The fully threaded design substantially improves pull-out strength compared to suture anchors with protruding eyelets. The fully threaded design prevents anchor “pull-back” that may occur with countersunk anchors, which is especially advantageous when poor quality bone is encountered.

The Bio-Corkscrew FT has a unique FiberWire eyelet recessed into the body of the anchor which reduces suture abrasion at the eyelet during knot tying.

The Bio-Corkscrew FT's strong internal square head drive mechanism substantially increases resistance to stripping during insertion to hard cortical bone. The Bio-Corkscrew Punch is always used to prepare a bone socket prior to insertion of the anchor. In most cases, no tapping will be needed prior to the anchor being implanted. When extreme cortical bone is present, the Cutting Tap for Bio-Corkscrew FT is used.

The Bio-Corkscrew FT comes preloaded with two #2 FiberWire sutures, one blue and one white/black, for easier suture management. The implant is also available with two 26 mm 1/2 circle cutting needles swedged on each suture for open procedures.

Bio-Corkscrew FT Suture Anchor, 5.5 mm x 15 mm, w/ two #2 FiberWire, sterile, qty. 5, *SU* (a)

AR-1927BF

Bio-Corkscrew FT Suture Anchor w/ Needles, 5.5 mm x 15 mm, w/ two #2 FiberWire with 26 mm 1/2 circle needles, sterile, qty. 5, *SU*

AR-1927BNF

U.S. PATENT NOS. 5,964,783; 6,716,234 and PATENT PENDING

Required Instrumentation:

Bio-Corkscrew Punch, 5 mm


AR-1920PB

Bio-Corkscrew Cutting Punch, 5 mm (b)

AR-1920CPB

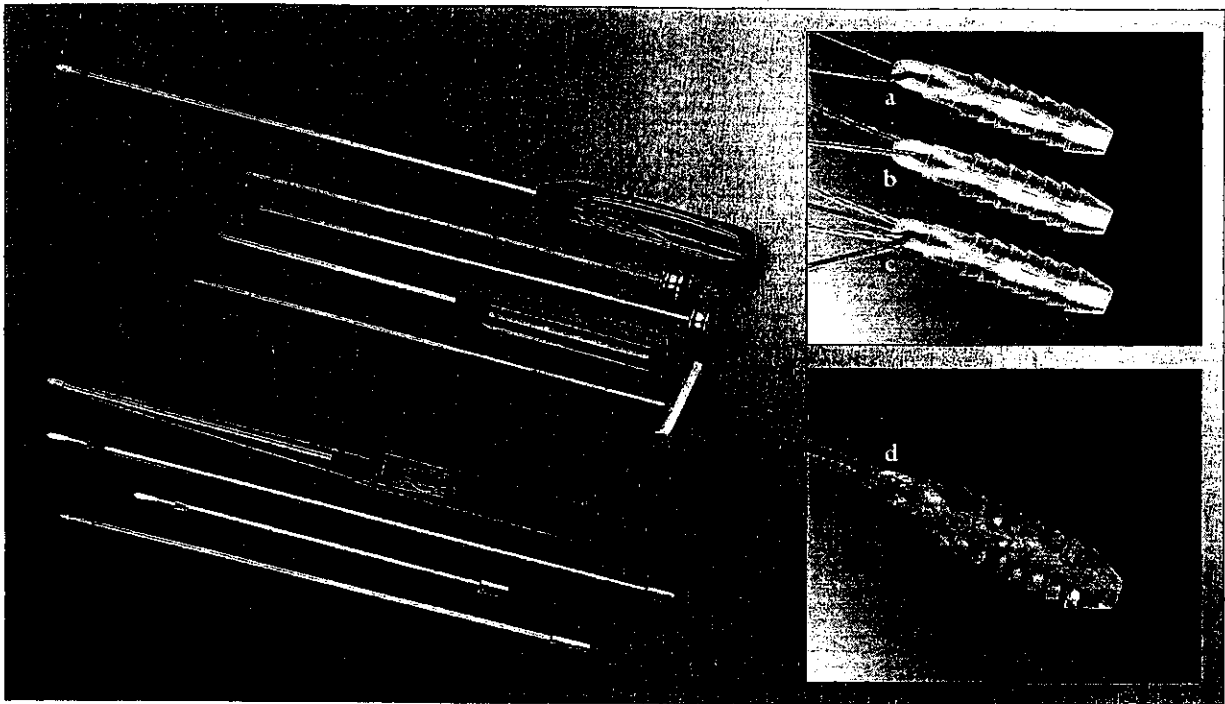
Cutting Tap for Bio-Corkscrew FT (c)

AR-1927CTB

Actual Size of 5.5 mm 



Bio-SutureTak™ Suture Anchor



Key Words: Push-in bioabsorbable suture anchor, plication suture option, molded-in suture eyelet eliminates suture abrasion

The Bio-SutureTak is a 3 mm bioabsorbable "push-in" suture anchor with a molded-in suture eyelet ideal for soft tissue attachment to bone in the shoulder joint and other indications where a small anchor profile with high pull-out strength is required. The exclusive braided suture eyelet loop is molded into the body of the anchor and provides superior resistance to suture abrasion compared to conventional metal anchors. This unique eyelet design allows the attached suture to slide smoothly enhancing the performance of arthroscopic sliding-knots. The Bio-SutureTak is available with either one or two #2 FiberWire sutures or with one polyester Tevdek suture. For use in softer bone and revisions, the Bio-SutureTak is also available in a 3.7 mm diameter. All of the Bio-SutureTaks are sterile, single use and preloaded on a disposable handled inserter for speed and convenience.

A needle version of the Bio-SutureTak is also available. It is recommended that the optional Short Spade Tip Drill and optional Short Spear be used with the Bio-SutureTak w/Needles. The Spear with Trocar and Blunt Obturator is used for percutaneous insertion or through a cannula. A Blunt Tip Obturator is also in the instrument set. The Bio-SutureTak Punch can be used to make a small pilot hole and to provide a coined surface to avoid skiving of the drill which is always used. Two other cannulated inserters are available: the Offset Clear Guide and the Clear Guide.

Implants and Accessories:

Bio-SutureTak, 3 mm x 14 mm, qty. 5 (a)
 Bio-SutureTak w/#2 FiberWire, 3 mm x 14 mm, qty. 5
 Bio-SutureTak w/two #2 FiberWire, 3 mm x 14 mm, qty. 5 (c)
 Bio-SutureTak w/#2 TigerTail, 3 mm x 14 mm, qty. 5 (b)
 Bio-SutureTak w/Needles, 3 mm x 14 mm, w/#2 FiberWire, qty. 5
 Bio-SutureTak, 3.7 mm x 14 mm, w/#2 FiberWire, qty. 5 (d)
 Short Spade Tip Drill (use with AR-1326G)
 Spade Tip Drill, thick shaft
 Spade Tip Drill
 Short Spear (used with AR-1256)
 Plication Driver, sterile, SU
 Step Drill (for 3 mm Bio-SutureTak) (required)
 Step Drill for 3.7 mm Bio-SutureTak (required)
 Clear Guide, sterile, SU
 Offset Clear Guide, sterile, SU
 Bio-SutureTak Disposables Kit, sterile, SU
 Bio-SutureTak Disposables Kit, w/metal Spear

AR-1934B
 AR-1934BF
 AR-1934BF-2
 AR-1934BFT
 AR-1934BNF
 AR-1934BLF
 AR-1256
 AR-1252
 AR-1257
 AR-1326G
 AR-1934DBS
 AR-1250LT
 AR-1908
 AR-1934CG
 AR-1934G
 AR-1934DS
 AR-1934DS-2

Bio-SutureTak Instrumentation Set, 3 mm (AR-1934S):

Spear with Trocar and Blunt Obturator	AR-1949
Blunt Tip Obturator	AR-1949-02
Bio-SutureTak Punch	AR-1934P
Bio-SutureTak Instrumentation Case	AR-1934C

Bio-SutureTak Instrumentation Set, 3.7 mm (AR-1934LS):

Bio-SutureTak Spear, 3.7 mm, reusable	AR-1907
Bio-SutureTak Instrumentation Case	AR-1934C

U.S. PATENT NO. 6,716,234
 and PATENT PENDING

Actual Size of 3 mm

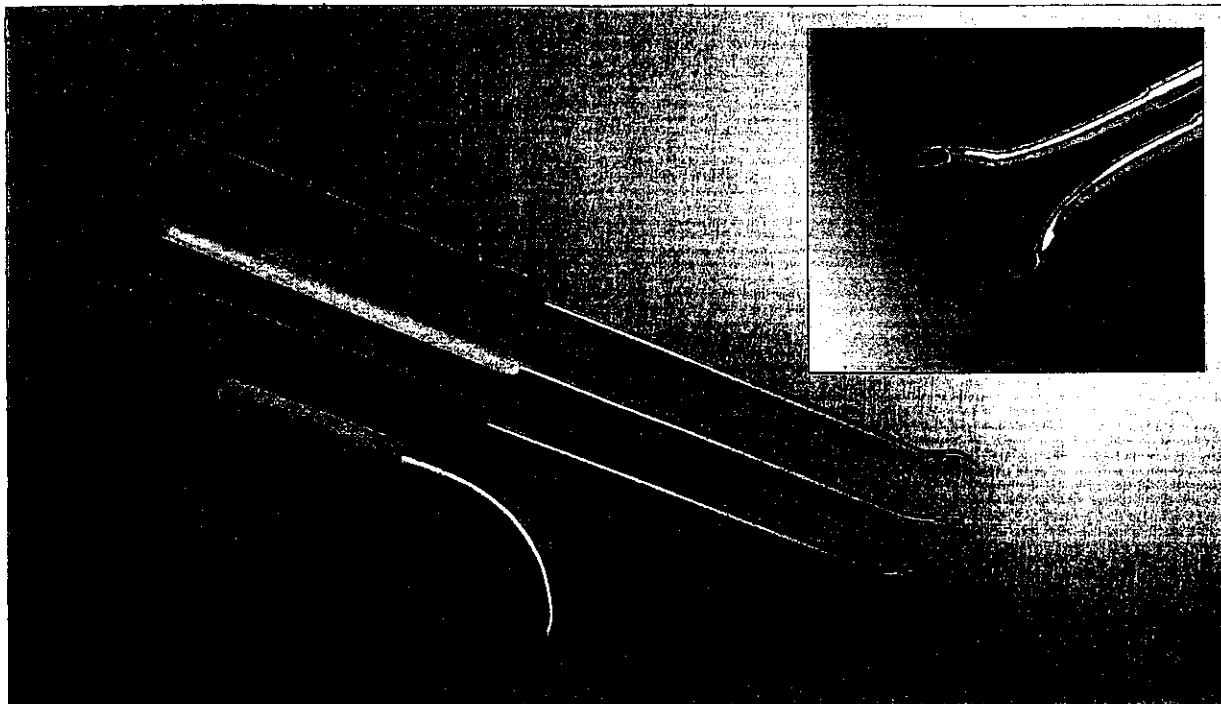
U.S. PATENT NO. 6,716,234 and PATENT PENDING

9-16 Shoulder Arthroscopy & Mini-Open Repairs

ARM 18489



SutureLasso™



Key Words: Arthroscopic shoulder repairs, less technically demanding, facilitates soft tissue suture placement, reproducible and accurate, single use, Nitinol loop

The SutureLasso is a single use suture shuttle instrument available in various curved tip configurations for arthroscopic Bankart, SLAP and rotator cuff repairs. Each Lasso comes preloaded with a Nitinol loop. The sharp tip and small diameter shaft will easily penetrate soft tissue while the reinforced shaft resists bending. After the tip is passed through soft tissue, the loop is deployed and retrieved through a cannula with a Crochet Hook or Suture Retriever. A suture strand or suture tail from a previously placed suture anchor is placed in the loop, and the opposite end of the loop is pulled, delivering the suture through tissue and out the cannula. The Corkscrew SutureLasso, 45° curve right, should be used for anterior labral reconstruction of the right shoulder.

The Banana SutureLasso is designed for rotator cuff suturing from a superior, percutaneous approach (Modified Neviaser Portal).

Banana SutureLasso, sterile, SU	AR-4065B
SutureLasso, 45° w/Wire Loop, sterile, SU	AR-4065W
SutureLasso, 90° w/Wire Loop, sterile, SU	AR-4065-90W
Corkscrew SutureLasso, 45° curve right, sterile, SU	AR-4065-45R
Corkscrew SutureLasso, 45° curve left, sterile, SU	AR-4065-45L

Designed in conjunction with Stephen S. Burkhart, M.D., San Antonio, TX, and James E. Tibone, M.D., Inglewood, CA.

Recommended Accessories:

Crochet Hook	AR-5008H
Push/Pull Crochet Hook	AR-5009H
Suture Retriever, 3.4 mm, straight	AR-12540
Suture Retriever, 3.4 mm, 15° up	AR-12550
Suture Retriever, 3.4 mm, 45° right	AR-12580
Suture Retriever, 3.4 mm, 45° left	AR-12590
KingFisher Suture Retriever/Tissue Grasper	AR-13970SR
FiberStick, #2 FiberWire, 50 inches (blue) one end stiffened, 12 inches, sterile, qty. 5, SU	AR-7209
#2 TigerStick, #2 TigerWire, 50 inches (white/black) one end stiffened, 12 inches, sterile, qty. 5, SU	AR-7209T
2-0 FiberStick, 2-0 FiberWire, 50 inches (blue) one end stiffened, 12 inches, sterile, qty. 5, SU	AR-7222

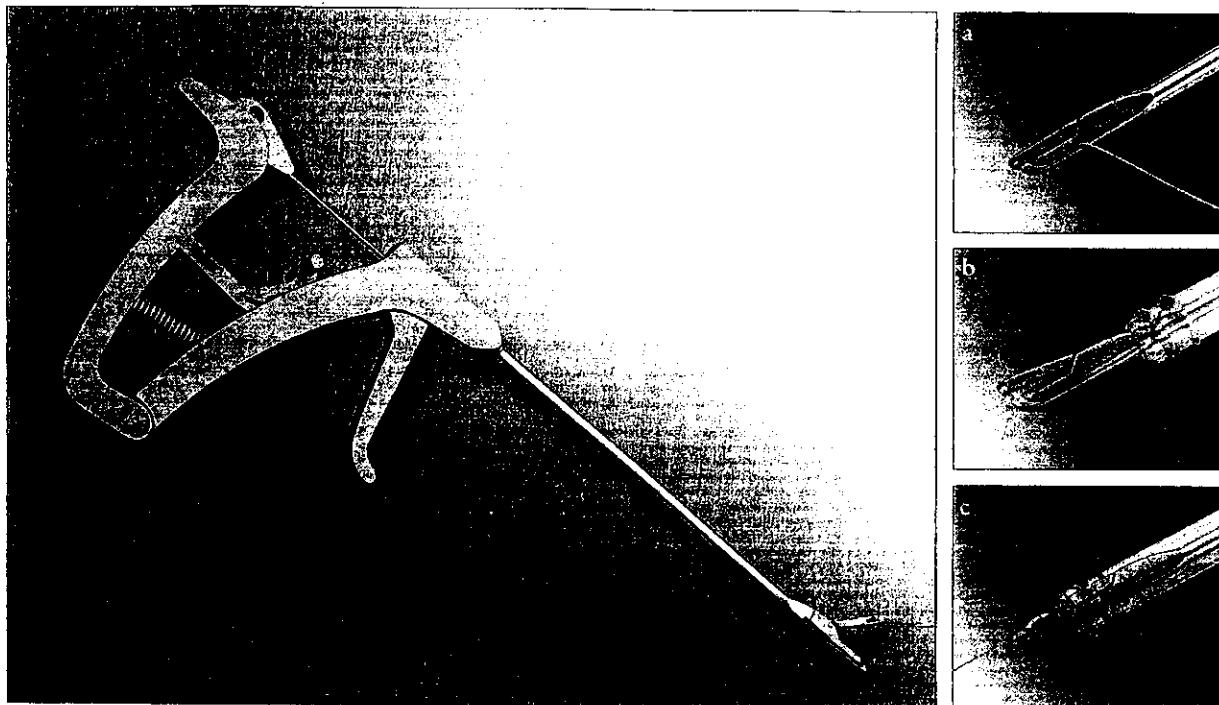
PATENT PENDING

9-20 Shoulder Arthroscopy & Mini-Open Repairs

ARM 18493



NeedlePunch™ II



Key Words: Arthroscopic needle passing, simple, reproducible suture passing, 7 mm cannula, precisely engineered, lifetime guarantee

The NeedlePunch II is a simple, versatile and effective suture passing instrument with a new ergonomic handle and push rod. The low profile design allows it to fit through a 7 mm diameter cannula. The lower jaw has more taper for easier placement under the rotator cuff tissue. The instrument enables the surgeon to reduce soft tissue and place a stitch up to 1 cm medial to the edge of the tissue in one quick step.

The NeedlePunch needle comes pre-loaded on Bio-Corkscrew Suture Anchors for suture passing without a shuttle step. The FiberWire Loop with NeedlePunch needle is a #2 FiberWire suture with a loop at the end to shuttle an anchor suture through soft tissue. The NeedlePunch Suture Shuttle is a NeedlePunch needle with a small loop of 2-0 FiberWire attached allowing direct passage of the anchor suture through tissue. The #2 FiberWire with two NeedlePunch needles is for side-to-side rotator cuff repairs.

A needle is loaded into the bottom jaw of the instrument and the back handle is squeezed slightly locking the needle into place. Once the desired bite of tissue is grasped, deploy the needle through the cuff by squeezing the back handle. The needle comes up through the soft tissue and locks into the catch mechanism on the upper jaw. To remove the needle, open the jaw and remove the needle by sliding it towards the hinge.

NeedlePunch II
NeedlePunch II Push Rod Replacement

AR-13981S
AR-13981P

NeedlePunch Accessories:

FiberWire Loop w/Needle for NeedlePunch, 26 inches, sterile, qty. 12, SU
#2 FiberWire w/two Needles for NeedlePunch, sterile, qty. 12, SU
Suture Shuttle, 40 mm, sterile, qty. 5, SU
Bio-Corkscrew Suture Anchor w/NeedlePunch Needles, 5 mm x 17.9 mm,
w/handled inserter and two #2 FiberWire, sterile, qty. 5, SU
Bio-Corkscrew Suture Anchor w/NeedlePunch Needles, 6.5 mm x 17.9 mm,
w/handled inserter and two #2 FiberWire, sterile, qty. 5, SU

AR-7204
AR-7207
AR-7224
AR-1920BNP
AR-1925BNP

U.S. PATENT NO. 6,716,234 and PATENT PENDING

Recommended Cannula:

Partially Threaded Cannula, 7 mm x 7 cm, sterile, qty. 5, SU

AR-6567

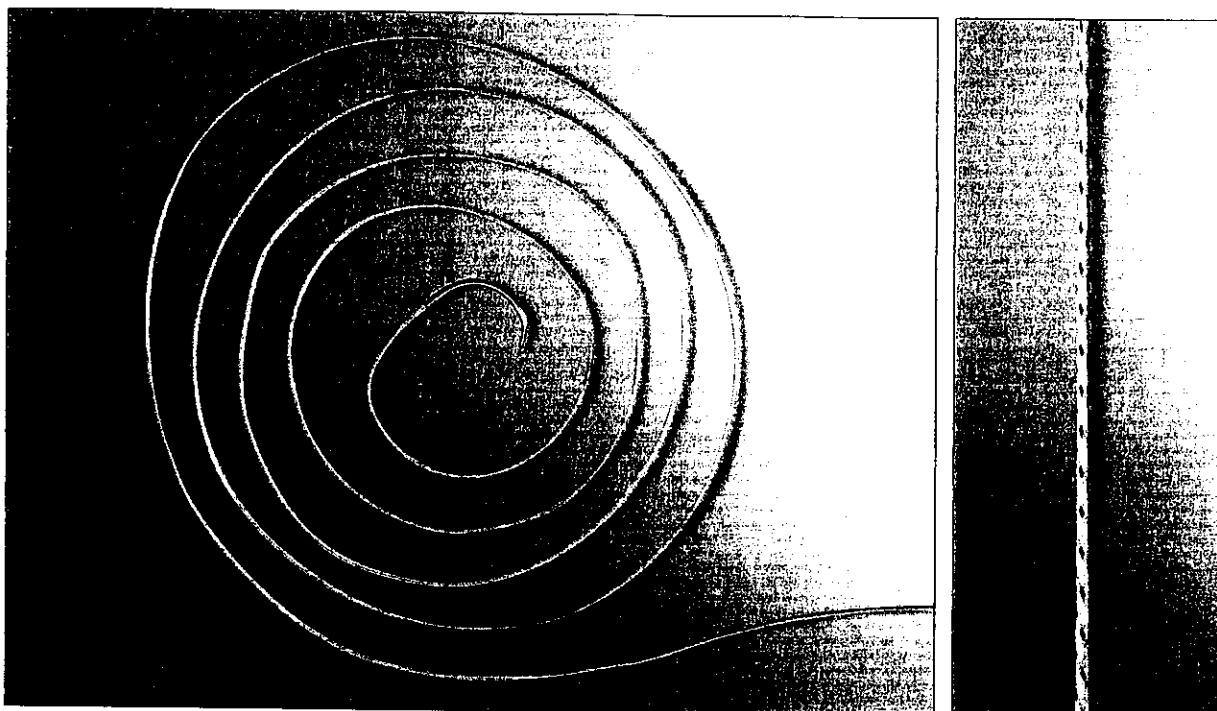
Designed in conjunction with John K. Morris, M.D., Ann Arbor, MI, and Stephen S. Burkhart, M.D., San Antonio, TX.

9-22 Shoulder Arthroscopy & Mini-Open Repairs

ARM 18495



FiberWire® and TigerWire®



Key Words: Size #2 with the strength of #5, new composite material technology, abrasion resistant, designed for most orthopaedic reconstruction procedures

FiberWire suture is a new generation of polyester suture with a long chain polyethylene core. FiberWire has greater strength than similar sized polyester suture with superior feel, smooth tie ability and lower knot profile. FiberWire is the ideal suture for most orthopaedic soft tissue repairs, virtually eliminating suture breakage during knot tying.

#2 TigerWire, a white suture with black spiral markings, was created specifically for arthroscopic surgeons that require superior suture visibility, easier arthroscopic orientation and motion determination.

All sizes of FiberWire have greater strength than polyester suture with the same diameter, with smoother feel and tie ability. Cyclic loading of #2 FiberWire resulted in 1,000,000 cycles without failure compared to 160,000 cycles of standard #2 polyester to failure. All FiberWire and TigerWire are sterile and single use.

#2 FiberWire, 38 inches (blue) w/Tapered Needle, 26.5 mm 1/2 circle, qty. 12	AR-7200
#2 FiberWire, 38 inches, 2 strands (1 blue, 1 white/black), qty. 12	AR-7201
#2 FiberWire, 38 inches (blue) w/Reverse Cutting Needle, 36.6 mm 1/2 circle, qty. 12	AR-7202
#2 TigerWire, 38 inches (white/black), qty. 12 (a)	AR-7203
#2 FiberWire, 38 inches (blue) w/two Tapered Needles, 26.5 mm 1/2 circle, qty. 12	AR-7205
#2 TigerWire, 38 inches (white/black) w/two Tapered Needles, 26.5 mm 1/2 circle, qty. 12	AR-7205T
#2 FiberWire, 38 inches (1 blue, 1 white/black) w/Tapered Needle, 26.5 mm 1/2 circle, qty. 12	AR-7208
#5 FiberWire, 38 inches (blue), qty. 12	AR-7210
#5 FiberWire, 38 inches w/Conventional Cutting Needle, 48 mm 1/2 circle, qty. 12	AR-7211
2-0 FiberWire, 18 inches (blue) w/Tapered Needle, 17.9 mm 3/8 circle, qty. 12	AR-7220
2-0 FiberWire, 38 inches (blue), qty. 12	AR-7221
3-0 FiberWire, 18 inches (blue) w/Diamond Point Needle, 26.2 mm 3/8 circle, qty. 12	AR-7225
3-0 FiberWire, 18 inches (blue) w/Tapered Needle, 15 mm 3/8 circle, qty. 5	AR-7227-01
3-0 FiberWire, 18 inches (blue) w/RC Needle, 16.3 mm 3/8 circle, qty. 5	AR-7227-02
4-0 FiberWire, 18 inches (blue) w/ Diamond Point Needle, 18.7 mm 3/8 circle, qty. 12	AR-7228
4-0 FiberWire, 18 inches (blue) w/Tapered Needle, 12.3 mm 3/8 circle, qty. 5	AR-7230-01
4-0 FiberWire, 18 inches (blue) w/RC Needle, 11.9 mm 3/8 circle, qty. 5	AR-7230-02
0 FiberWire, 38 inches (blue) w/Tapered Needle, 22.2 mm 1/2 circle, qty. 5	AR-7250
0 FiberWire, 38 inches (blue) w/Diamond Point Needle, 22.2 mm 1/2 circle, qty. 5	AR-7251

U.S. PATENT NO. 6,716,234

Orthopaedic Specialty Suture 12-1

ARM 18533



FiberWire® Suture Kit



Key Words: Convenient, compact, variety of sizes, easy suture differentiation

The FiberWire Suture Kit is available for larger complex soft tissue approximation procedures. This kit contains a total of 18 sutures including three different colored versions of #5 FiberWire for easy suture differentiation, large cutting Spring Eye Free Needles, and #2 FiberWire in one convenient package.

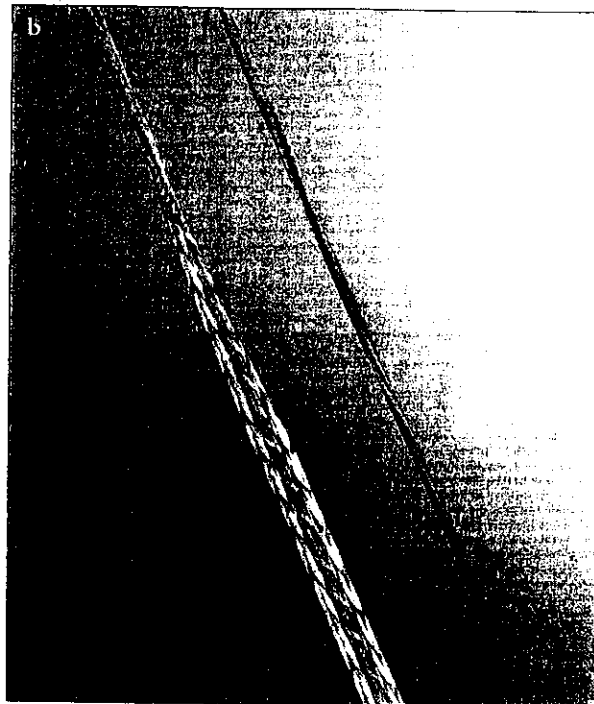
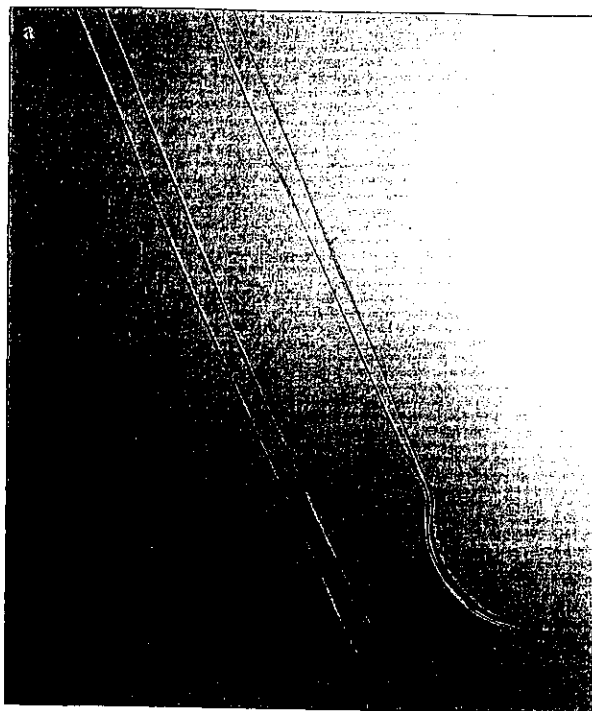
FiberWire Suture Kit (AR-7219) sterile, SU includes:

- #5 FiberWire, 38 inches (blue), qty. 4
- #5 FiberWire, 38 inches (white), qty. 4
- #5 TigerWire, 38 inches (white/black), qty. 4
- #2 FiberWire, 38 inches (blue) w/ Tapered Needle, qty. 6
- Free Needle, Spring Eye, 80 mm, qty. 2
- Free Needle, Spring Eye, 60 mm, qty. 1

U.S. PATENT NO. 6,716,234



FiberLoop™ and FiberTape™



Key Words: Size 4-0 FiberWire, swedged-on tapered needle

FiberLoop is a suture option for multi-strand tendon repairs. These small diameter looped FiberWire products allow for strong multi-strand flexor and extensor tendon repairs while reducing tendon damage from multiple needle passes. FiberLoop is available with multiple needle options to prevent cutting suture while stitching.

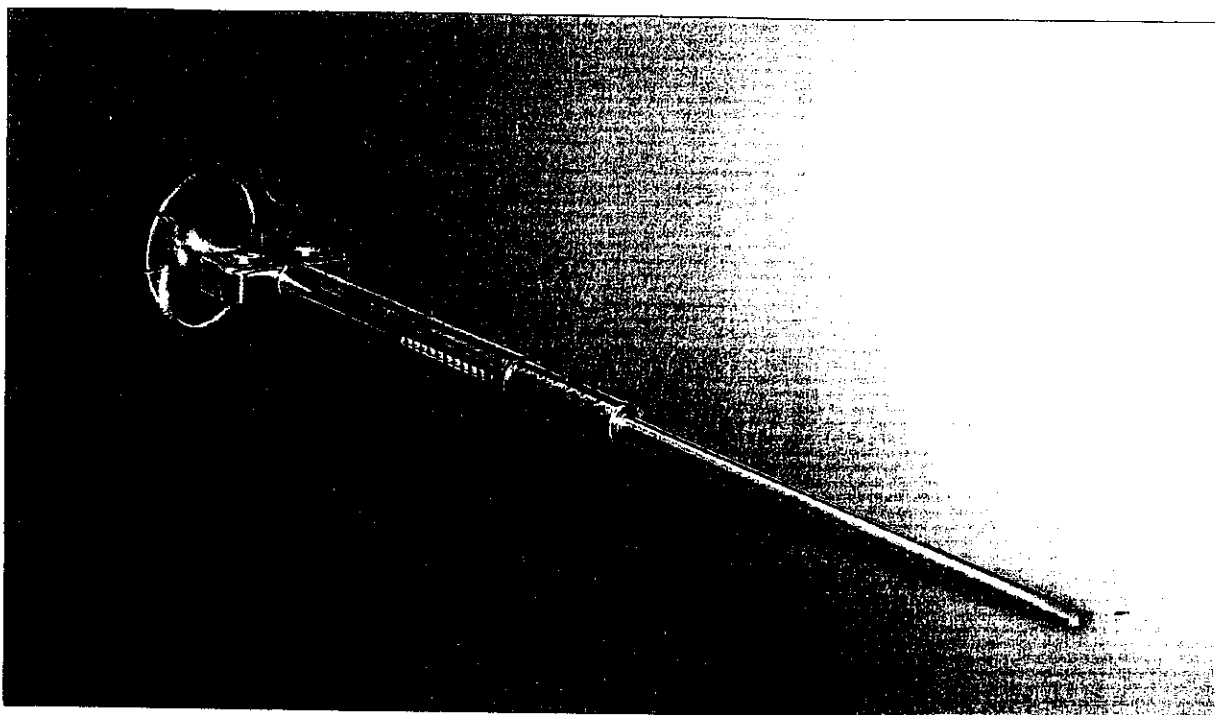
FiberTape is an ultra-high strength 2 mm width tape using the long chain polyethylene structure of the FiberWire suture. The broad footprint of the FiberTape is appropriate for repairs in degenerative cuff tissue where tissue pull-through may be a concern.

4-0 FiberLoop, 4-0 FiberWire, 12 inches (blue) w/Tapered Needle, 17.9 mm 3/8 circle, sterile, qty. 12, SU (a)	AR-7229-12
4-0 FiberLoop, 4-0 FiberWire, 20 inches (blue) w/Tapered Needle, 17.9 mm 3/8 circle, sterile, qty. 12, SU	AR-7229-20
2-0 FiberLoop, 60 inches (blue) w/Diamond Point Needle, 48 mm 1/2 circle, sterile, qty. 12, SU	AR-7232-01
2-0 FiberLoop, 48 inches (blue) w/Diamond Point Needle, 26.2 mm 3/8 circle, sterile, qty. 12, SU	AR-7232-02
2-0 FiberLoop, 30 inches (blue) w/Diamond Point Straight Needle, 64.8 mm, sterile, qty. 12, SU	AR-7232-03
FiberTape, 2 mm, 54 inches (blue) each end tapered to #2 FiberWire, 8 inches, sterile, qty. 12, SU (b)	AR-7237

U.S. PATENT NO. 6,716,234



FiberWire® Tensioner



Key Words: Arthroscopic FiberWire tensioning, open procedures

The FiberWire Tensioner provides controlled tensioning of FiberWire loops during knot tying when reapproximating bone-to-bone or soft tissue-to-bone. The blunt tip keeps the knot in place while the tensioning wheel and spring mechanism gently tension the loop to tighten the repair. It is ideal for use in conjunction with #5 FiberWire during tuberosity reapproximation of proximal humerus fractures, patellar fracture reduction and fixation, and olecranon fracture reduction and fixation.

It is recommended that the FiberWire Tensioner be used in conjunction with sliding knots. Once the FiberWire is passed through all planes of tissue/bone, the appropriate sliding knot is tied and advanced to the tissue level. One limb of the FiberWire suture is passed up through the cannulation of the FiberWire Tensioner shaft, with the aid of a Suture Passing Wire, and loaded into the slot and locking post on the tensioning wheel to keep it in place. The tensioning wheel is then turned in a counterclockwise fashion as the tension meter is read. Once the desired amount of tension/reduction is achieved, three reverse half-hitches can be thrown down the barrel of the tensioner to secure the fixation.

FiberWire Tensioner

AR-1929

PATENT PENDING

Designed in conjunction with Anthony A. Romeo, M.D., Chicago, IL.

Accessories:

Suture Passing Wire, sterile, SU

AR-1255-18

FiberWire Suture Kit, sterile, SU

AR-7219

Recommended Suture (sterile, SU):

#2 FiberWire, 38 inches w/Tapered Needle, 26.5 mm 1/2 circle, qty. 12

AR-7200

#2 FiberWire, 38 inches, 2 strands (1 blue, 1 white/black), qty. 12

AR-7201

#2 FiberWire, 38 inches w/Reverse Cutting Needle, 36.6 mm 1/2 circle, qty. 12

AR-7202

#5 FiberWire, 38 inches, qty. 12

AR-7210

#5 FiberWire, 38 inches w/Conventional Cutting Needle, 48 mm 1/2 circle, qty. 12

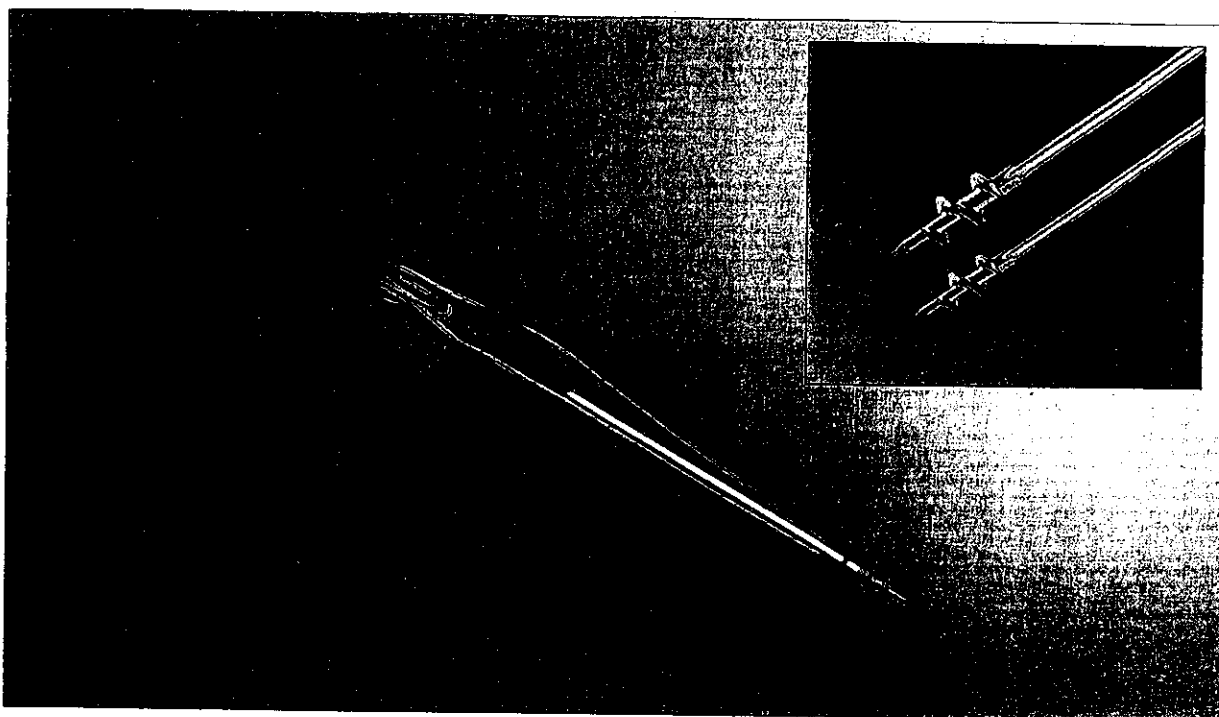
AR-7211

Orthopaedic Specialty Suture 12-7

ARM 18539



Small Joint Corkscrew™ Suture Anchor



Key Words: Soft tissue anchoring, open foot and ankle repair and reconstruction, Achilles, posterior tibial tendon, Kidner, Brostrom, lateral ankle stabilization, biceps repair, cancellous threads, FiberWire, two sutures, two needles

The Small Joint Corkscrew is available in 3.5 mm and 5 mm diameters. They are specifically designed with shorter inserter shafts, FiberWire and needles for open procedures of the foot, ankle, hand, wrist and elbow. They incorporate a small minor diameter with a cancellous thread pattern that maximizes pull-out strength. The sharp conical tip ensures positioning on bone and ease of starting will be accomplished with little effort. A horizontal laser mark visible on the driver shaft indicates when the anchor is fully seated in the bone. The anchors are supplied sterile with two strands of FiberWire, each with diamond tip needles.


A Corkscrew Starter Awl is available should the surgeon encounter very hard bone. The awl requires either the Tear Drop Handle (AR-2001) or the Ratcheting Screwdriver Handle (AR-1999). A Reusable Corkscrew Handle is available for surgeons who prefer a larger handle design.

Corkscrew Suture Anchor w/Needles, 3.5 mm x 15 mm,
w/handled inserter and two #0 FiberWire, sterile, qty. 5, *SU*
Corkscrew Suture Anchor w/Needles, 5.0 mm x 15 mm,
w/handled inserter and two #2 FiberWire, sterile, qty. 5, *SU*

AR-1915SNF

AR-1920SNF

U.S. PATENT NOS. 6,117,162; 6,214,031 and 6,511,499

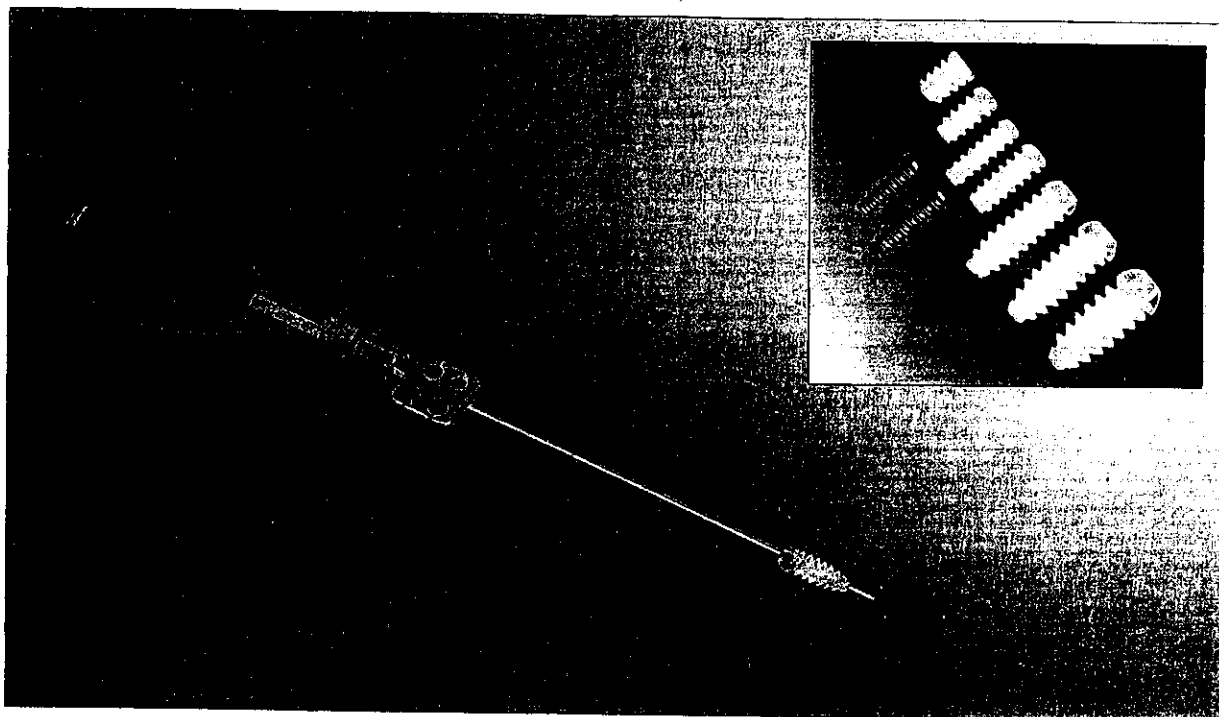
Actual Size of 5.0 mm 

Small Joint Repair 14-3

ARM 18548



Tenodesis™ Screws and Disposables



Key Words: Bioabsorbable PLLA Screw, ligament or tendon-to-bone repairs, eliminates transosseous tunnel graft tensioning, biceps tenodesis, collateral ligament repairs and reconstructions, ACL backup fixation

The Tenodesis Screws, used in conjunction with the Bio-Tenodesis Screw System, are available in PLLA and titanium. They are specifically designed for ligament or tendon-to-bone repairs or reconstructions utilizing both interference screw and suture anchor fixation principles. The round screw head provides protection of the graft after insertion. The Tenodesis Screw may also be used for suture fixation alone when used in conjunction with #2 or 2-0 FiberWire to facilitate intraoperative tissue shifting and tensioning. PLLA or titanium Tenodesis Screw insertion provides secure fixation for proximal and distal biceps reconstruction, collateral ligament repairs or reconstructions, ACL backup fixation and other intraarticular and extraarticular reconstructions in the shoulder, elbow, knee, foot and ankle. To maximize fixation, the graft passing sutures can be tied over the screw after insertion.

Bio-Tenodesis Disposables Kit (AR-1675DS), sterile, qty. 5, SU:
includes one each of the following:

Drill Tip Guide Pin, 2.4 mm
Suture Passing Wire
#2 FiberWire, 38 inches (blue) w/Tapered Needle, 26.5 mm 1/2 circle
#2 TigerWire, 38 inches (white/black)

AR-1250L
AR-1255-18
AR-7200
AR-7203

Bio-Tenodesis Screw System Implants, sterile, SU:

Bio-Tenodesis Screw, 4 mm x 10 mm
Bio-Tenodesis Screw, 4.75 mm x 15 mm
Tenodesis Screw, titanium, 5.5 mm x 15 mm
Tenodesis Screw, titanium, 4.75 mm x 15 mm
Bio-Tenodesis Screw, 5.5 mm x 15 mm
Bio-Tenodesis Screw, 6.25 mm x 15 mm
Bio-Tenodesis Screw, 7 mm x 23 mm
Bio-Tenodesis Screw, 8 mm x 23 mm
Bio-Tenodesis Screw, 9 mm x 23 mm
Bio-Tenodesis Screw, 7 mm x 10 mm
Bio-Tenodesis Screw, 8 mm x 12 mm

AR-1540B
AR-1547B
AR-1350-55
AR-1350-475
AR-1555B
AR-1562B
AR-1570B
AR-1580B
AR-1590B
AR-1670B
AR-1680B

Designed in conjunction with Neal ElAttrache, M.D., Los Angeles, CA, and Stephen S. Burkhart, M.D., San Antonio, TX.

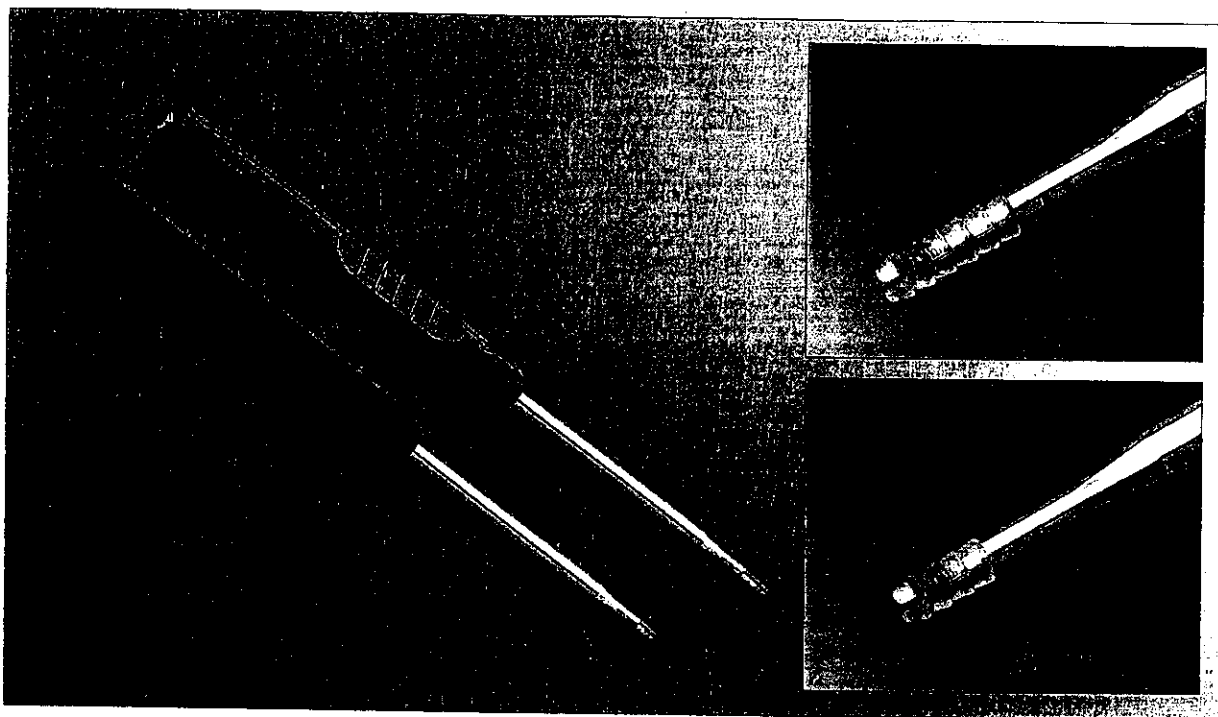
U.S. PATENT NO. 6,544,281

Small Joint Repair 14-5

ARM 18550



V-Tak™ and Mini V-Tak™



Key Words: PLDLA implant, handled inserter, small joint, FiberWire, forked distal tip, ligament and tendon repair

The V-Tak and Mini V-Tak are bioabsorbable implants used in small joint applications for soft tissue-to-bone repairs. The V-Tak is 2.2 mm x 7 mm and the Mini V-Tak is 2.2 mm x 4.7 mm and both come on their own handled inserters. The bioabsorbable PLDLA amorphous copolymer retains its initial fixation strength throughout the tissue-healing period of 12 weeks, and undergoes a rapid degradation process without causing a local soft tissue reaction. The anchor fully degrades in approximately 16 months.

The V-Tak and Mini V-Tak, with its unique forked distal tip, were designed to capture a FiberWire suture prethrown through soft tissue. As the anchor is inserted into a predrilled hole, the suture/tissue combination is fixated in the hole rather than on the surface of the bone. This low profile, quick, easy-to-place anchor will be especially useful in soft tissue reattachment in the hand, wrist, foot and ankle.

Primary uses include UCL and RCL repair of the thumb, carpal ligament repair in the wrist and midfoot reconstructions. The use of 3-0 FiberWire is recommended.

Mini V-Tak, 2.2 mm x 4.7 mm, sterile, qty. 5, *SU*

V-Tak, 2.2 mm x 7 mm, sterile, qty. 5, *SU*

V-Tak Disposables Instrument Kit, sterile, qty. 5, *SU*

Mini V-Tak Disposables Instrument Kit, sterile, qty. 5, *SU*

AR-8730B

AR-8735B

AR-8735DS

AR-8730DS

Recommended Suture:

3-0 FiberWire, 18 inches (blue) w/Tapered Needle, 15 mm 3/8 circle, sterile, qty. 12, *SU*

AR-7227-01

PATENT PENDING

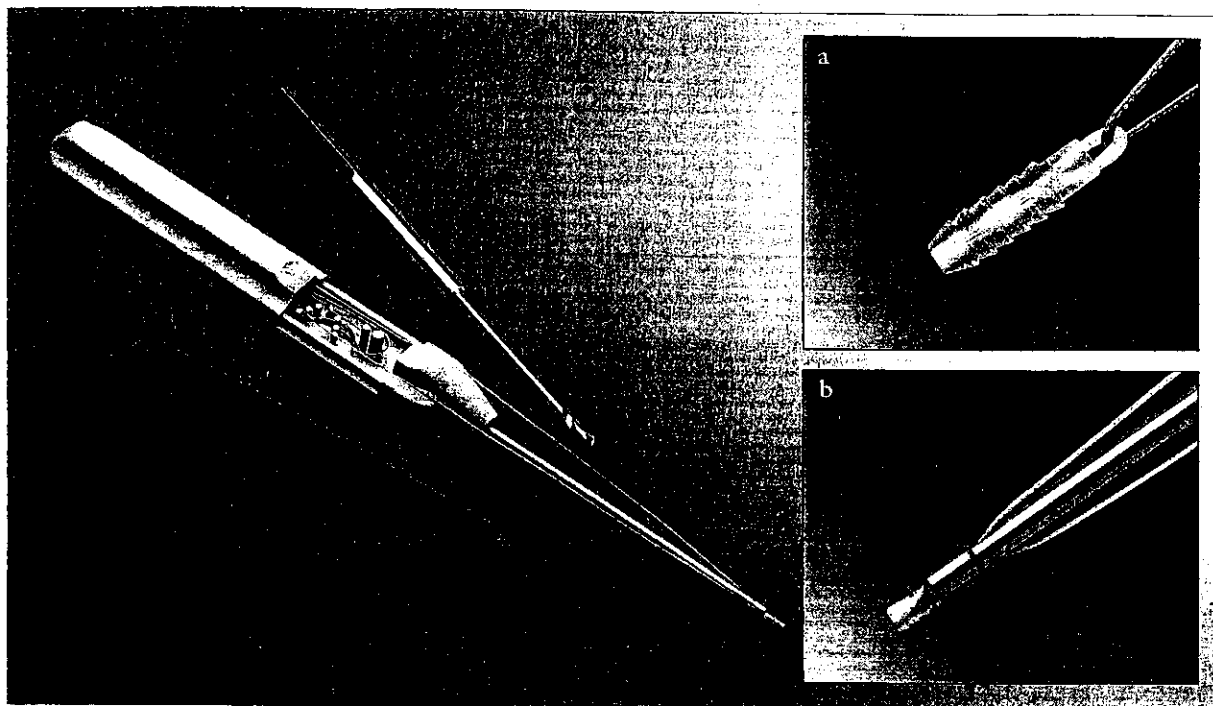
Actual Sizes

Small Joint Repair 14-7

ARM 18552



Mini and Micro Bio-SutureTak™ w/Needles



Key Words: PLDLA, delicate ligament and tendon repairs, hand, wrist and elbow, foot and ankle, FiberWire suture, low profile

The Mini and Micro Bio-SutureTaks are bioabsorbable PLDLA amorphous copolymer anchors that retain their initial fixation strength throughout the tissue healing process, and then undergo a rapid degradation process. They are available loaded with 2-0 FiberWire nonabsorbable composite suture and two 17.9 mm 3/8 circle needles for delicate ligament and tendon repairs in the hand, wrist, elbow, foot and ankle.

The Mini Bio-SutureTak is a 2.4 mm outer diameter x 7 mm length anchor. This low profile, easy-to-place anchor will be especially useful in UCL repair of the thumb, scapholunate ligament repairs in the wrist, lateral ankle ligament repairs, and capsular reattachment and closure following Hallux Valgus reconstruction.

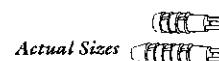
The Micro Bio-SutureTak is a 2.4 mm outer diameter x 5 mm length anchor and will be especially useful in digital collateral ligament repairs and tendon reattachments in the hand and foot.

Mini Bio-SutureTak w/Needles, 2.4 mm x 7 mm, w/handled inserter and 2-0 FiberWire, sterile, qty. 5, <i>SU</i> (a)	AR-1322BNF
Micro Bio-SutureTak w/Needles, 2.4 mm x 5 mm, w/handled inserter and 2-0 FiberWire, sterile, qty. 5, <i>SU</i> (b)	AR-1320BNF

Required Instrumentation:

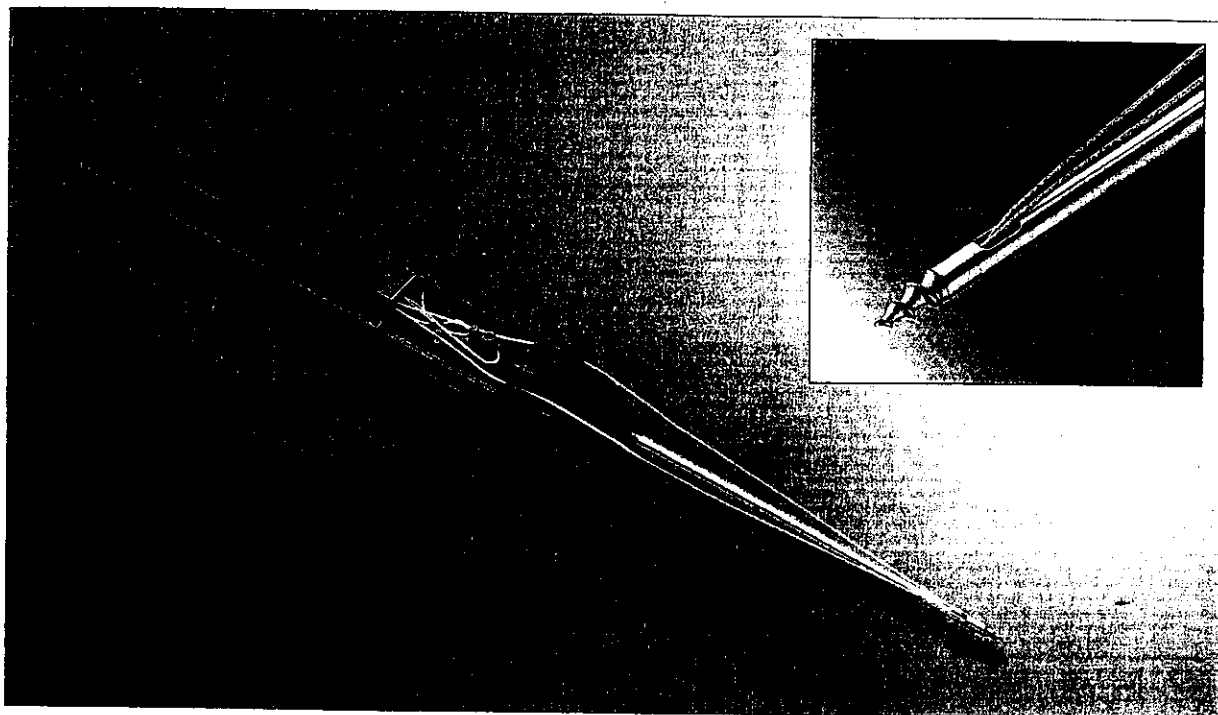
Mini Bio-SutureTak Disposable Instrument Set, <i>SU</i>	AR-1322DS
Micro Bio-SutureTak Disposable Instrument Set, <i>SU</i>	AR-1320DS

U.S. PATENT NO. 5,964,783





Small Bone FASTak™ Suture Anchor



Key Words: Soft tissue fixation, no predrilling, swedged-on needles, hand insertion, small bone, small joint

The Small Bone FASTak is a fully threaded 2.4 mm x 7.5 mm titanium suture anchor that is preloaded with 2-0 FiberWire. It comes on a handled inserter with two 17.9 mm 3/8 circle swedged-on tapered needles.

The Small Bone FASTak is screwed directly into bone without predrilling. It is designed for use in the hand, wrist and elbow for soft tissue reattachment procedures such as UCL repair of the thumb, ligament repair for scapholunate disassociation in the wrist, as well as ECRB repair in Tennis Elbow debridement. This device can also be used to repair lateral ankle ligaments for a modified Brostrom procedure.

A recent study has shown that threaded screw-in suture anchors have significantly more fixation strength than the Nitinol arc "barbed" suture anchors. Threaded screw-in suture anchors further reduce the risk of tissue separation from the point of fixation due to anchor slip.

Small Bone FASTak Suture Anchor, 2.4 mm x 7.5 mm
w/handled inserter and 2-0 FiberWire, sterile, qty. 5, SU

AR-1322-752SF

U.S. PATENT NO. 5,683,401 and PATENT PENDING

Actual Size

Small Joint Repair 14-11

ARM 18556

Arthrex Products Matrix of Label Product&Development codes

B Hallett ...NOVEMBER 2005

Percentage of Suture (Approx.)														
Braid - Sleeve					Core				Percentage of Suture (Approx.)					
Suture Spool Label	Pearsalls Product Code	Development construction code	Product	Size	Yarn Type	Dtex	Number of yarns	Yarn Type	Dtex	Number of yarns	Ply	UHMWPE	Polyester	Nylon
4-0B-F/W	37G153000	PS30	Blue Fibervire	4 / 0	UHMWPE Polyester	55 33	4 4	N/A	N/A	N/A	N/A	62.5%	37.50%	N/A
3-0B-F/W	37G203000	PSC33	Blue Fibervire	3 / 0	UHMWPE Polyester	55 49	4 4	UHMWPE	55	1	0	58.4%	41.6%	N/A
2-0B-F/W	37G302000	PS12/2	Blue Fibervire	2 / 0	UHMWPE Polyester	111 61	4 4	UHMWPE	144	1	0	70.7%	29.3%	N/A
0B-F/W	37G351000	DT3-5-3	Blue Fibervire	0	UHMWPE Polyester	111 61	6 6	UHMWPE	217	1	0	70.7%	29.3%	N/A
0W-F/W	38G351000	PS3-5-3	White Fibervire	0	UHMWPE Polyester	111 61	6 6	UHMWPE	217	1	0	70.7%	29.3%	N/A
1B-F/W	37G401000	PS53	Blue Fibervire	1	UHMWPE Polyester	144 113	6 6	UHMWPE	144	1	3	65.7%	34.3%	N/A
1W-T/W	36G401000	PS54	White Tigervire	1	UHMWPE Polyester	144 95	6 5	UHMWPE	144	1	3	70.1%	25.7%	4.2%
1B-T/W	36G401000BLUE	PS55	Blue Tigervire	1	UHMWPE Polyester	144 95	6 5	UHMWPE	144	1	3	70.1%	25.7%	4.2%
2B-F/W	37G500500	PS0512	Blue Fibervire	2	UHMWPE Polyester	144 95	8 8	UHMWPE	144	1	3	67.6%	32.4%	N/A
2W-F/W	38G500500	PS05W	White Fibervire	2	UHMWPE Polyester	144 95	8 8	UHMWPE	144	1	3	67.6%	32.4%	N/A
2W-T/W	36G500500	PSN14Na	White Tigervire	2	UHMWPE Polyester	144 95	8 7	UHMWPE	144	1	3	68.1%	28.6%	3.4%
U/T 2W-F/W	38A500500	PS05WU-a	White untreated Fibervire	2	UHMWPE Polyester	144 95	8 8	UHMWPE	144	1	3	67.6%	32.4%	N/A
5B-F/W	37G700250	PS07	Blue Fibervire	5	UHMWPE Polyester	217 190	8 8	UHMWPE	217	2	3	66.7%	33.3%	N/A
5W-F/W	38G700250	PSH 1/1	White Fibervire	5	UHMWPE Polyester	217 190	8 8	UHMWPE	217	2	3	66.7%	33.3%	N/A
5W-T/W	36G700250	PSNH 1	White Tigervire	5	UHMWPE Polyester	217 190	8 6	UHMWPE	217	2	3	70.1%	26.3%	3.6%
See Note Below	See Note Below	PSH 1	Green Fibervire	5	UHMWPE Polyester	217 190	8 8	UHMWPE	217	2	3	66.7%	33.3%	N/A
3+4W-F/W	38A600500	PS 34	White Fibervire	3/4	UHMWPE Polyester	217 190	6 6	UHMWPE	144	1	3	60.3%	39.7%	N/A
3+4B-F/W	38G600500	PS 34A	Blue Fibervire	3/4	UHMWPE Polyester	217 190	6 6	UHMWPE	144	1	3	60.3%	39.7%	N/A

DEPUY MITEK
EXHIBIT 318
04cv12457

See Note Below	See Note Below	PS67A	White / Black Tiger Tail	1	UHMWPE Polyester Nylon	144 95 78	6 6 1	UHMWPE	144	1	3	66.7%	29.3%	4.0%
See Note Below	See Note Below	PS67B	Blue / Black Tiger Tail	1	UHMWPE Polyester Nylon	144 95 78	6 6 1	UHMWPE	144	1	3	66.7%	29.3%	4.0%
2W-T/T-46	PSDH5-38 PSDH3-38	PSDH5-38A PSDH3-38A	White / Black Tiger Tail	2	UHMWPE Polyester Nylon	144 95 78	8 8 1	UHMWPE	144	1	3	65.4%	31.4%	3.2%
2B-T/T-46	PSDH5-38 PSDH3-38	PSDH5-38B PSDH3-38B	Blue / Black Tiger Tail	2	UHMWPE Polyester Nylon	144 95 78	8 8 1	UHMWPE	144	1	3	65.4%	31.4%	3.2%
SPD-02-01B	96G-500-500	DPM1	Blue Fiberwire	2	PURITY Polyester	110 113	8 8	PURITY	165	1	3	60.3%	39.7%	N/A
SPD-02-01W	96G-500-500	DPM02	White Fiberwire	2	PURITY Polyester	110 113	8 8	PURITY	165	1	3	60.3%	39.7%	N/A
SPD-02-01TW	97G-500-500	DPM03	White Tigerwire	2	PURITY Polyester Nylon	110 113 78	8 7 1	PURITY	165	1	3	61.3%	35.2%	3.5%

FiberWire is a suture with an outer covering of Ultra High Molecular Weight Polyethylene (UHMWPE) and polyester braided over an UHMWPE core.

TigerWire is a version of white FiberWire suture with a black strand creating spiral markings along the entire length of the suture.

Tiger Tail is a version of FiberWire suture with a black strand that creates spiral markings along one-half the length of the suture.

NOTE

Suture Spool Label and Pearlsails Product Code have not been assigned to these products.

PRODUCT CODE IDENTIFICATION

UNTREATED	A	
MED COATED	G	
BLUE	37	
WHITE	38	
TIGERWIRE	36	Please state blue if required

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a
Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware
Corporation,

Defendant.

DEPOSITION OF:

PETER DREYFUSS

DATE:

September 16, 2005

TIME:

8:59 a.m. to 1:54 p.m.

LOCATION:

The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112

TAKEN BY:

Plaintiff

REPORTER:

Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER:

Les Smoak, CLVS

<p style="text-align: right;">30</p> <p>1 A. Yes.</p> <p>2 Q. Is it true then that the No. 2 FiberWire used in</p> <p>3 AR-7201 has the same braiding as any Arthrex product that</p> <p>4 has a No. 5 FiberWire in it?</p> <p>5 A. Yes.</p> <p>6 Q. Is it true then that the No. 2 FiberWire used in</p> <p>7 AR-7201 has the same braiding as any Arthrex product that</p> <p>8 has a No. 2-0 FiberWire in it?</p> <p>9 A. Yes.</p> <p>10 Q. Is it true then that the No. 2 FiberWire used in</p> <p>11 AR-7201 has the same braiding as any Arthrex product that</p> <p>12 has a 0 FiberWire in it?</p> <p>13 A. I believe so.</p> <p>14 Q. Is it true then that the No. 2 FiberWire used in</p> <p>15 AR-7201 has the same braiding as any Arthrex product that</p> <p>16 has a 2 -- Strike that. Let me rephrase that.</p> <p>17 Is it true then that the No. 2 FiberWire used in</p> <p>18 AR-7201 has the same braiding as any Arthrex product that</p> <p>19 has a 3-0 FiberWire in it?</p> <p>20 A. I don't know.</p> <p>21 Q. And who would know that?</p> <p>22 A. Tara Schaneville.</p> <p>23 Q. Okay. Is it true then that the No. 2 FiberWire</p> <p>24 used in AR-7201 has the same braiding as any Arthrex</p> <p>25 product that has a 4-0 FiberWire used in it?</p>	<p style="text-align: right;">32</p> <p>1 FiberWire?</p> <p>2 A. The braid, no.</p> <p>3 Q. Are the materials used in any Arthrex TigerWire</p> <p>4 different than the braid -- than the materials used in</p> <p>5 Arthrex's No. 2 FiberWire?</p> <p>6 MR. TAMBURRO: Object to the form.</p> <p>7 A. Yes.</p> <p>8 Q. And how are they different?</p> <p>9 A. There is a strand -- one carrier of PET is</p> <p>10 replaced by one carrier of nylon.</p> <p>11 Q. Is that only difference in the braid between</p> <p>12 Arthrex's TigerWire products of any size and Arthrex's No</p> <p>13 2 FiberWire?</p> <p>14 A. Yes.</p> <p>15 Q. So the coating is the same; is that right?</p> <p>16 A. Yes.</p> <p>17 Q. And the coating used on all Arthrex FiberWire</p> <p>18 products, TigerWire products is MED-2174; right?</p> <p>19 A. Yes.</p> <p>20 Q. Has any other coating been used by Arthrex at any</p> <p>21 time to coat any of Arthrex's FiberWire products or</p> <p>22 TigerWire products?</p> <p>23 A. No.</p> <p>24 MR. FALKE: Sal, during the course of the break,</p> <p>25 do you think you could try to contact Tara Schaneville</p>
<p style="text-align: right;">31</p> <p>1 A. I don't know.</p> <p>2 Q. And Tara would also know that?</p> <p>3 A. Correct.</p> <p>4 Q. Okay. Other than the No. 2, 5, 0, 2-0, 3-0, and</p> <p>5 4-0, are there any other size FiberWires sold by Arthrex?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. What other sizes of FiberWire other than</p> <p>8 2, 5, 0, 0-2, 0-3 -- Yeah, strike that.</p> <p>9 What other sizes other than 5, 2, 0, 2-0, 3-0,</p> <p>10 and 4-0 are sold by Arthrex?</p> <p>11 A. A FiberTape.</p> <p>12 Q. Okay. Anything else?</p> <p>13 A. No.</p> <p>14 Q. And is the braid of TigerWire different than the</p> <p>15 braid used in the No. 2 FiberWire?</p> <p>16 MR. TAMBURRO: Object to the form.</p> <p>17 Q. Do you understand the question?</p> <p>18 A. Yes.</p> <p>19 Q. Okay.</p> <p>20 A. Yes.</p> <p>21 Q. They are different?</p> <p>22 A. The braid in -- I'm sorry. Please rephrase or</p> <p>23 repeat.</p> <p>24 Q. Sure. Sure. Is the braid in any Arthrex</p> <p>25 TigerWire different than the braid used in Arthrex's No. 2</p>	<p style="text-align: right;">33</p> <p>1 to try to find the answer to I think the three</p> <p>2 questions of 2-0, 3-0 --</p> <p>3 MS. VERRECCHIO: No, not 2-0.</p> <p>4 MR. FALKE: Not 2-0. Right. 3-0, 4-0, and 0</p> <p>5 just to find out if the braid used in those sizes is</p> <p>6 the same as No. 2.</p> <p>7 MR. TAMBURRO: The same as No. 2?</p> <p>8 MR. FALKE: Right.</p> <p>9 MR. TAMBURRO: Sure.</p> <p>10 MR. FALKE: Thanks.</p> <p>11 Why don't we -- Can we take a break now and try</p> <p>12 to find out, because that will help out.</p> <p>13 MR. TAMBURRO: Sure.</p> <p>14 VIDEOGRAPHER: Going off the record. We're off</p> <p>15 (A short break was held from 9:46 a.m. to 9:58</p> <p>16 a.m.)</p> <p>17 VIDEOGRAPHER: Back on the record.</p> <p>18 BY MR. FALKE:</p> <p>19 Q. Over the break, did you have a chance to talk to</p> <p>20 Tara Schaneville?</p> <p>21 A. Yes.</p> <p>22 Q. Is the No. 0 FiberWire constructed -- Strike</p> <p>23 that.</p> <p>24 Is the No. 0 FiberWire braided the same as</p> <p>25 the No. 2 FiberWire in AR-7201?</p>

<p>38</p> <p>1 Q. How many carriers are used in the braiding and 2 manufacturing of any Arthrex 2-0 FiberWire regardless of 3 whether it's attached to a needle or an anchor or is a 4 free-standing strand?</p> <p>5 A. Eight.</p> <p>6 Q. How many carriers are used in the braiding and 7 manufacturing of Arthrex's 3-0 FiberWire regardless of 8 whether it's attached to an anchor or a suture or a 9 needle?</p> <p>10 A. Eight.</p> <p>11 Q. And how many carriers are used in the braiding 12 and manufacturing of Arthrex's 4-0 FiberWire suture 13 regardless of whether it's attached to an anchor or a 14 needle?</p> <p>15 A. Eight.</p> <p>16 Q. So the Size 2-0, 3-0, and 4-0 FiberWire sutures 17 used by Arthrex all use eight carriers in the braiding and 18 manufacturing of them?</p> <p>19 A. Correct.</p> <p>20 Q. And the No. 2 FiberWire suture, No. 5 FiberWire 21 suture, the No. 0 FiberWire suture, the No. 2-0 FiberWire 22 suture, and the 3-0 FiberWire suture all have the same 23 braiding process; right?</p> <p>24 A. Yes.</p> <p>25 Q. And the No. 4-0 FiberWire suture has a different</p>	<p>40</p> <p>1 A. No. As a whole, no.</p> <p>2 Q. You've seen parts of it though?</p> <p>3 A. I believe so.</p> <p>4 Q. Okay. If you could turn to ARM 8784, please, in 5 Exhibit 102. Have you seen ARM 8784 in Exhibit 102 6 before?</p> <p>7 A. No, I haven't.</p> <p>8 Q. Do you know what is shown on ARM 8784 in 9 Exhibit 102?</p> <p>10 A. It appears to be a flow chart for manufacturing 11 at Pearsalls.</p> <p>12 Q. Can you take a look at and review ARM 8784 for 13 me.</p> <p>14 A. (Witness nods head affirmatively). Yes.</p> <p>15 Q. Do you have an understanding of how Pearsalls 16 braids the bulk suture used in Arthrex's FiberWire sutures 17 and suture products?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. And do you believe that the process flow 20 chart on ARM 8784 accurately depicts the braiding process 21 that Pearsalls uses to braid and manufacture the bulk 22 sutures used in Arthrex's FiberWire sutures and suture 23 products?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. Currently, what materials are used in the</p>
<p>39</p> <p>1 braiding process than the 2, 5, 0, 2-0, and 3-0; right?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And other than the 2, 5, 0, 2-0, 3-0, and 4 4-0, are there any other size FiberWire that Arthrex 5 sells?</p> <p>6 A. Yes.</p> <p>7 Q. What other sizes?</p> <p>8 A. FiberTape.</p> <p>9 Q. Okay. And does FiberTape have a size?</p> <p>10 A. Two-millimeter FiberTape.</p> <p>11 Q. Okay. We'll get into FiberTape later.</p> <p>12 And I think we established earlier that the 13 braiding of any size FiberLoop, FiberStick, FiberSnare is 14 the same as the braid used in the No. 2 FiberWire suture 15 in AR-7201; right?</p> <p>16 MR. TAMBURO: Objection; mischaracterizes prior 17 testimony.</p> <p>18 A. As I understand, yes.</p> <p>19 Q. Okay. Did you understand that question?</p> <p>20 A. Yes.</p> <p>21 Q. I believe you have in front of you Exhibit 102?</p> <p>22 A. Yes.</p> <p>23 Q. Could you look at that, please.</p> <p>24 If you could, please -- Well, first, have you 25 ever seen Exhibit 102 before?</p>	<p>41</p> <p>1 manufacture of Arthrex's No. 2 FiberWire in AR-7201?</p> <p>2 A. Ultra high molecular weight polyethylene, PET, 3 silicone, and cyanoacrylate.</p> <p>4 Q. Is it cyanoacrylate?</p> <p>5 A. Acrylate. It's a Superglue, Loc-Tite.</p> <p>6 Q. Okay. Any other materials used in the 7 manufacture of Arthrex's No. 2 FiberWire?</p> <p>8 A. Dye.</p> <p>9 Q. Okay. Anything else?</p> <p>10 A. Not that I'm aware of.</p> <p>11 Q. Okay. So as far as you know, the only 12 materials -- as far as Arthrex is aware, the only 13 materials used to make Arthrex's No. 2 FiberWire in 14 AR-7201 is ultra high molecular weight polyethylene, PET, 15 silicone, Loc-Tite, and dye?</p> <p>16 A. And if we're speaking of TigerWire, nylon.</p> <p>17 Q. Okay. We're not talking TigerWire. We're just 18 talking No. 2 FiberWire in AR-7201.</p> <p>19 A. 7201 includes TigerWire.</p> <p>20 Q. That's right. That's why I have been saying the 21 No. 2 FiberWire in 7201.</p> <p>22 A. They're both No. 2s.</p> <p>23 Q. Right, but one's a TigerWire and one's a 24 FiberWire; right?</p> <p>25 A. Yes, the blue FiberWire in 7201.</p>

<p style="text-align: right;">42</p> <p>1 Q. Okay. Okay. When I have been saying today the 2 No. 2 FiberWire in No. 7201, I have been referring to the 3 blue FiberWire as opposed to the black and white 4 TigerWire. 5 A. Understood. 6 Q. Okay. Did you understand that when I have been 7 asking questions? 8 A. Yes, I have. 9 Q. Okay. Let me ask the question again. So as 10 Arthrex believes the materials used in the manufacturing 11 of the No. 2 FiberWire in AR-7201 are ultra high molecular 12 weight polyethylene, PET, silicone, Loc-Tite, and dye? 13 A. Correct. 14 Q. And the silicone, is that the coating used in the 15 No. 2 Arthrex FiberWire? 16 A. Yes. 17 Q. And what coating is used in Arthrex's FiberWire 18 in AR-2 -- AR-7201? 19 A. I'm sorry. I -- 20 Q. And what coat is used in Arthrex's FiberWire wire 21 AR-7201? 22 A. I believe it's a silicone coating. 23 Q. Is it referred to as MED-2174? 24 A. Yes. Correct. 25 Q. And that's manufactured by a company called NuSil</p>	<p style="text-align: right;">44</p> <p>1 A. Currently -- 2 Q. Let me ask another question to help you out. 3 Does Arthrex provide to Pearsalls the ultra high molecular 4 polyethylene used to manufacture and braid bulk sutures 5 for Arthrex's FiberWires? 6 MR. TAMBURIO: Same objection. 7 A. We have, yes. 8 Q. Currently do you; do you know? 9 A. Currently, I don't know. 10 Q. Okay. And other than Arthrex supplying the ultra 11 high molecular polyethylene to Pearsalls, what other 12 sources throughout the history of FiberWire has Pearsalls 13 obtained the ultra high molecular weight polyethylene used 14 in the manufacturing and braiding of Arthrex's FiberWire 15 sutures? 16 MR. TAMBURIO: Objection. The question is seeking 17 an answer outside the scope of the topics that this 18 witness is designated for. 19 A. I believe Dyneema. DSM Corporation. 20 Q. And for what periods did Pearsalls obtain Dyneema 21 for use in the braiding and manufacturing of Arthrex's 22 FiberWire sutures? 23 MR. TAMBURIO: Same objection. 24 A. I don't know. 25 Q. Currently, what type of ultra high molecular</p>
<p style="text-align: right;">43</p> <p>1 Technologies; is that right? 2 A. That's correct. 3 Q. Okay. Now I'd like to walk through the steps of 4 what Pearsalls does to make the bulk sutures used in 5 Arthrex's FiberWire; okay? 6 A. (Witness nods head affirmatively). 7 Q. And if we start on Page ARM 8784, the first step 8 says incoming yarn to stores. Do you see that? 9 A. Yes. 10 Q. What does that mean? 11 A. That would mean that the yarns that are purchased 12 from a regional manufacturer would be received, inspected 13 and put into inventory for -- as good product for 14 manufacturing. 15 Q. And what incoming yarns are received by Pearsalls 16 when Pearsalls manufactures and braids the bulk sutures 17 made for Arthrex's FiberWire sutures? 18 A. Incoming yarns would be ultra high molecular 19 weight polyethylene and PET. 20 Q. Where does Pearsalls obtain the ultra high 21 molecular weight polyethylene used in manufacturing and 22 braiding Arthrex's FiberWire sutures? 23 MR. TAMBURIO: Objection; outside the scope. 24 A. I -- May I ask currently? 25 Q. Sure. Yes, currently for now.</p>	<p style="text-align: right;">45</p> <p>1 polyethylene is used in the manufacturing of Arthrex's 2 FiberWire sutures? 3 A. Speaking currently, it may be either Spectra or 4 Dyneema in terms of the manufacture of the ultra high 5 molecular weight polyethylene. 6 THE COURT REPORTER: The "manufacture"? 7 A. Of the procurement. 8 THE COURT REPORTER: "Procurement." 9 Q. But you're not sure what the current material 10 used in the FiberWire is for ultra high molecular 11 polyethylene? 12 A. No. 13 Q. Okay. Other than the ultra high molecular 14 polyethylene that Pearsalls obtains to make the braid for 15 Arthrex's FiberWire sutures, you mentioned that they also 16 obtain PET; correct? 17 A. Correct. 18 Q. And what is PET? 19 A. It's polyester. 20 Q. And what type of polyester does Pearsalls use to 21 braid Arthrex's FiberWire sutures? 22 A. I'm not sure. 23 Q. Do you know who or where Pearsalls obtains the 24 PET used in the manufacturing of Arthrex's FiberWire 25 sutures?</p>

12 (Pages 42 to 45)

<p style="text-align: right;">50</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And then let's get back to where we were.</p> <p>3 Yarn issue to winding for either. And I believe you said</p> <p>4 that Pearsalls then takes the incoming yarn in whatever</p> <p>5 form it's in and puts the polyester and the Dyneema or the</p> <p>6 polyethylene on various bobbins?</p> <p>7 A. Yes.</p> <p>8 MR. TAMBURIO: Objection.</p> <p>9 Q. Is that right?</p> <p>10 MR. TAMBURIO: I'm going to object; that</p> <p>11 mischaracterizes the testimony.</p> <p>12 Q. Did I mischaracterize your testimony?</p> <p>13 A. The yarn is issued to winding for winding onto a</p> <p>14 particular spool or bobbin that would aid in the</p> <p>15 manufacturing steps that would come thereafter.</p> <p>16 Q. Mmm-hmm. Is the ultra high molecular -- Is the</p> <p>17 polyethylene and the PET when it's received by Pearsalls</p> <p>18 is the strand a monofilament?</p> <p>19 MR. TAMBURIO: Object to the form.</p> <p>20 A. No.</p> <p>21 Q. What is -- How do you characterize that strand of</p> <p>22 polyethylene when Pearsalls receives it?</p> <p>23 MR. TAMBURIO: Object to the form.</p> <p>24 A. It is a various -- various individual filaments</p> <p>25 make up the yarn that's received. And the yarn may be</p>	<p style="text-align: right;">52</p> <p>1 A. I'm not exactly sure on exactly how the yarn is</p> <p>2 received, so --</p> <p>3 MR. TAMBURIO: And I would clarify the witnesses's</p> <p>4 prior testimony has been ultra --</p> <p>5 MR. FALKE: Is that an objection? Come on, Sal.</p> <p>6 MR. TAMBURIO: Yes, this is an objection. I would</p> <p>7 clarify that the witness's prior testimony has been</p> <p>8 polyethylene -- ultra high molecular weight</p> <p>9 polyethylene, and your questions are directed to</p> <p>10 something different.</p> <p>11 And his prior testimony has stated that PET is</p> <p>12 used in FiberWire, and your questions are rephrasing</p> <p>13 that term, was well. I'm just trying to keep the</p> <p>14 record clear.</p> <p>15 BY MR. FALKE:</p> <p>16 Q. What is PET? Polyester; right?</p> <p>17 A. PET is the particular polyester.</p> <p>18 Q. So when I say polyester, I'm referring to the PET</p> <p>19 that's used in Arthrex's FiberWire sutures.</p> <p>20 A. Yeah.</p> <p>21 MR. TAMBURIO: Is that a question?</p> <p>22 Q. Yeah.</p> <p>23 MR. TAMBURIO: Okay.</p> <p>24 A. If you're saying when you refer to polyester, we</p> <p>25 refer to -- it's referring to the PET.</p>
<p style="text-align: right;">51</p> <p>1 several filaments to many.</p> <p>2 Q. So what is an individual filament then?</p> <p>3 A. An individual filament is -- you would liken it</p> <p>4 to a hair.</p> <p>5 Q. Okay.</p> <p>6 A. An individual filament would be a monofilament</p> <p>7 taken by itself.</p> <p>8 Q. Okay. And then many monofilaments make up a</p> <p>9 yarn?</p> <p>10 A. Correct.</p> <p>11 Q. And how are they -- how were the monofilaments</p> <p>12 structured within the yarn?</p> <p>13 A. I believe they may have a slight twist.</p> <p>14 Q. Okay. So a yarn of polyethylene used in the</p> <p>15 FiberWire sutures is made up of many monofilaments twisted</p> <p>16 around each other --</p> <p>17 MR. TAMBURIO: Objection; assumes --</p> <p>18 Q. -- is that fair?</p> <p>19 MR. TAMBURIO: Objection; assumes facts not in</p> <p>20 evidence. I object to the form.</p> <p>21 A. Potentially.</p> <p>22 Q. Have I assumed any facts in that question that we</p> <p>23 haven't talked about today?</p> <p>24 MR. TAMBURIO: Well, I would just --</p> <p>25 MR. FALKE: I'm asking the witness.</p>	<p style="text-align: right;">53</p> <p>1 Q. Right, because when I asked you what PET was, you</p> <p>2 said polyester; right?</p> <p>3 A. No, PET is a subset of polyester.</p> <p>4 Q. Okay. But do you know what PET is used in the</p> <p>5 manufacturing of Arthrex's FiberWire sutures?</p> <p>6 A. I'm not exactly sure.</p> <p>7 Q. Okay. We were talking about how the individual</p> <p>8 monofilaments in the polyethylene or the ultra high</p> <p>9 molecular polyethylene are structured. And I think you</p> <p>10 said they were twisted; is that right?</p> <p>11 A. I believe there may be a slight twist just to</p> <p>12 ease in handling.</p> <p>13 Q. Okay. Okay. And then, again, down to the second</p> <p>14 step in ARM 8784, those strands are then put onto bobbins;</p> <p>15 is that what you said?</p> <p>16 A. Yes.</p> <p>17 Q. And what is a bobbin as used in ARM 8784?</p> <p>18 A. A bobbin as a general term would be any round --</p> <p>19 what would you call it --</p> <p>20 Q. Spool?</p> <p>21 A. -- a revolved shape that would allow you to wind</p> <p>22 something. It may or may not have end caps on it.</p> <p>23 Q. But the bobbin is actually the thing that the</p> <p>24 sutures are wound around?</p> <p>25 A. Sutures are wound around.</p>

<p>54</p> <p>1 Q. Okay.</p> <p>2 A. Sutures, yarn, what have not.</p> <p>3 Q. Right. In general, how big are these bobbins?</p> <p>4 A. In general?</p> <p>5 Q. Well, no. Let me ask the bobbins used in</p> <p>6 Pearsalls manufacture of Arthrex's FiberWire sutures, how</p> <p>7 big are the bobbins?</p> <p>8 A. I would approximate them -- approximate about a</p> <p>9 foot -- 12 inches of length or less.</p> <p>10 Q. Okay. And how -- and what length of the yarn of</p> <p>11 the PET and the ultra high molecular weight polyethylene</p> <p>12 are wound around the bobbins?</p> <p>13 A. I'm not exactly sure.</p> <p>14 Q. Okay. Generally?</p> <p>15 A. Generally, it's --</p> <p>16 Q. A hundred feet?</p> <p>17 A. More than a hundred feet. Probably in excess of</p> <p>18 2 or 300 meters.</p> <p>19 Q. Okay. And then it says yarn issue dye the</p> <p>20 winding for core or cover; do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. What does that mean?</p> <p>23 A. At that point, they can either issue the yarn to</p> <p>24 a winding to -- which would then thereafter go into the</p> <p>25 cover portion of the product or they can issue it to be --</p>	<p>56</p> <p>1 cover; right?</p> <p>2 A. Yes.</p> <p>3 Q. And currently -- currently, the Arthrex 4-0</p> <p>4 FiberWire suture does not have a core; right?</p> <p>5 A. Correct.</p> <p>6 Q. Has Arthrex's FiberWire suture -- 4-0 suture ever</p> <p>7 had a core?</p> <p>8 A. No, not that I'm aware of.</p> <p>9 Q. In Arthrex's FiberWire sutures presently, other</p> <p>10 than the 4-0 FiberWire, what is the core made of?</p> <p>11 A. Ultra high molecular weight polyethylene.</p> <p>12 Q. Is that it?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. So in Arthrex's FiberWires -- all of</p> <p>15 Arthrex's FiberWire sutures except for 4-0, the core is</p> <p>16 made of solely ultra high molecular weight polyethylene?</p> <p>17 A. Correct.</p> <p>18 Q. And what about a cover? What is -- Currently, I</p> <p>19 think you said all Arthrex FiberWire sutures have a cover;</p> <p>20 right?</p> <p>21 A. Yes.</p> <p>22 Q. What materials make up the cover in each of</p> <p>23 Arthrex's FiberWire sutures?</p> <p>24 A. Ultra high molecular weight polyethylene and PET.</p> <p>25 Q. And has that always been the case?</p>
<p>55</p> <p>1 to go to the process for the core.</p> <p>2 Q. Okay. And what -- does every Arthrex FiberWire</p> <p>3 suture have a cover?</p> <p>4 A. Yes.</p> <p>5 Q. Has every Arthrex FiberWire suture sold by</p> <p>6 Arthrex had a cover on it?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And currently and historically, has every</p> <p>9 Arthrex FiberWire suture had a core in it?</p> <p>10 A. No.</p> <p>11 Q. Okay. When did Arthrex's FiberWire sutures have</p> <p>12 a core?</p> <p>13 A. They have always had a core.</p> <p>14 Q. Do they -- Okay. I think I asked and currently</p> <p>15 and historically, has ever FiberWire suture had a core and</p> <p>16 you said no; right?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And then I said when -- when did Arthrex's</p> <p>19 FiberWire sutures have a core. And then you said they've</p> <p>20 always had a core.</p> <p>21 A. We have one product that does not have a core.</p> <p>22 Q. Okay. And what product is that?</p> <p>23 A. The 4-0 FiberWire.</p> <p>24 Q. Okay. So currently and historically, every</p> <p>25 FiberWire suture other than the 4-0 has had a core and a</p>	<p>57</p> <p>1 A. Yes.</p> <p>2 Q. But at various points and times, you think that</p> <p>3 the ultra high molecular polyethylene was either Dyneema</p> <p>4 or Spectra; is that right?</p> <p>5 A. Correct.</p> <p>6 Q. Was it anything other than Dyneema or Spectra at</p> <p>7 any time?</p> <p>8 A. Not that I'm aware of.</p> <p>9 Q. Okay. So I think where we are now is Pearsalls</p> <p>10 has taken the incoming yarn, put it onto bobbins, and then</p> <p>11 have separated bobbins used for cores and separates</p> <p>12 bobbins used for carriers; is that right? I mean cores</p> <p>13 and covers?</p> <p>14 A. Correct.</p> <p>15 Q. Okay. So let's go down then -- let's go down the</p> <p>16 cover side on ARM 8784. What does that mean?</p> <p>17 A. From the previous step, which was the yarn issue</p> <p>18 to winding, the yarn was issued to winding on the carrier</p> <p>19 bobbins which are the particular bobbins used for the</p> <p>20 carriers.</p> <p>21 Q. Is the carrier bobbin different than the bobbin</p> <p>22 you just described earlier?</p> <p>23 A. It's one of -- to me, a bobbin -- a bobbin and a</p> <p>24 spool might be different. A bobbin would have a post on</p> <p>25 it with no cap.</p>

15 (Pages 54 to 57)

<p>62</p> <p>1 Q. So this is back up to number one?</p> <p>2 A. Correct.</p> <p>3 Q. Okay.</p> <p>4 A. They're on --</p> <p>5 Q. The incoming yarn stage?</p> <p>6 A. -- placed onto pegs or posts to keep them, for</p> <p>7 lack of a better word, in a vertical fashion.</p> <p>8 Q. Okay.</p> <p>9 A. The yarns that are let off, how ever many there</p> <p>10 are, are let off and are led around turning posts.</p> <p>11 Q. Mmm-hmm.</p> <p>12 A. And then to the end -- to the bobbin or the spool</p> <p>13 that it's going to be taken up on. And as the yarns go</p> <p>14 around the posts, it naturally puts a twist in them</p> <p>15 together. They're going around the post in an unorthodox</p> <p>16 fashion, if you will.</p> <p>17 Q. Okay. So the twisting of the core yarns occurs</p> <p>18 with Pearsalls takes the incoming yarns and puts them on</p> <p>19 the bobbin?</p> <p>20 A. Yes. For the core.</p> <p>21 Q. Okay. So as shown on ARM 8784, do you see how it</p> <p>22 says twist after the yarn issue to winding for either; do</p> <p>23 you see that?</p> <p>24 A. Yes.</p> <p>25 Q. Is that right then or is that --</p>	<p>64</p> <p>1 on the size of the FiberWire suture; is that right?</p> <p>2 A. Correct.</p> <p>3 Q. Okay. And then like we talked about earlier,</p> <p>4 each individual yarn is composed of mono -- several</p> <p>5 monofilaments?</p> <p>6 A. Correct.</p> <p>7 Q. Okay. Now I believe we talked about the ultra</p> <p>8 high molecular weight polyethylene is a yarn that's</p> <p>9 composed of many monofilaments; is that right?</p> <p>10 A. Correct.</p> <p>11 Q. What about the polyester -- or the PET? How is</p> <p>12 the PET -- how is the yarn of PET structured?</p> <p>13 A. In the same fashion.</p> <p>14 Q. Same way? So the PET used in Arthrex's FiberWire</p> <p>15 sutures is in the form of yarn, and that PET yarn is made</p> <p>16 up of several twisted monofilaments of PET?</p> <p>17 A. Correct.</p> <p>18 Q. Okay. Okay. So right now we have in the</p> <p>19 manufacturing process -- and the steps we've talked about</p> <p>20 so far, does this apply to all of Arthrex's FiberWire</p> <p>21 sutures and TigerWire sutures?</p> <p>22 A. With the exception of the 4-0 suture.</p> <p>23 Q. Right. The only difference between the 4-0</p> <p>24 suture is that there's no core bobbin? It's just --</p> <p>25 A. Correct.</p>
<p>63</p> <p>1 A. That's correct.</p> <p>2 Q. So does the -- To me, I read that to mean first</p> <p>3 the yarns for the core are put onto a bobbin, and then</p> <p>4 after they're put on a bobbin, they're twisted?</p> <p>5 A. No, they --</p> <p>6 Q. That's not right?</p> <p>7 A. The yarns -- it's yarn issued to winding for</p> <p>8 either.</p> <p>9 Q. Okay.</p> <p>10 A. And then so the yarn is issued to a department.</p> <p>11 Q. Okay.</p> <p>12 A. That department receives those and would say --</p> <p>13 they would have the next work instruction, I would assume.</p> <p>14 Q. Mmm-hmm.</p> <p>15 A. The block called twist.</p> <p>16 Q. Mmm-hmm (affirmative).</p> <p>17 A. And they would say -- take these yarns, put them</p> <p>18 on these fixtures, apply the twist to them, how ever many</p> <p>19 yarns there are, and wind them to a bobbin, which would be</p> <p>20 the next bubble in the flow chart.</p> <p>21 Q. Okay. And so that bobbin down at the bottom is</p> <p>22 the core bobbin?</p> <p>23 A. Correct.</p> <p>24 Q. And that core bobbin contains a length of several</p> <p>25 different yarns that have been twisted together, depending</p>	<p>65</p> <p>1 Q. Okay. Now in the -- the bobbin used to make the</p> <p>2 cover, the individual yarns are not twisted together;</p> <p>3 right?</p> <p>4 A. Correct.</p> <p>5 Q. Okay. Could you initial or put your name on that</p> <p>6 and date it? And then use whatever title you think best</p> <p>7 describes what's shown in the picture. To me, it's</p> <p>8 incoming yarn to core bobbin, but if that's not accurate,</p> <p>9 please change it.</p> <p>10 A. Today's date is the --</p> <p>11 Q. 16th. I'm going to mark this Exhibit 117.</p> <p>12 (DePuy Mitek Exhibit No. 117, drawing by Peter</p> <p>13 Dreyfuss of Twisting Process for Core Production of</p> <p>14 FiberWire, was marked for identification.)</p> <p>15 Q. And could you draw then on -- I think I gave you</p> <p>16 another sheet of paper.</p> <p>17 A. Yes, you did.</p> <p>18 Q. Could you draw in just as much detail as you need</p> <p>19 the process from the incoming yarns to the bobbins used</p> <p>20 for the cover of the FiberWire sutures.</p> <p>21 A. That would be --</p> <p>22 Q. Or maybe just describe it with reference to</p> <p>23 Exhibit 117.</p> <p>24 A. The difference would be very simple. There's the</p> <p>25 cover yarns used in FiberWire are only one yarn.</p>

17 (Pages 62 to 65)

<p style="text-align: right;">98</p> <p>1 Q. And I don't know if you did, but could you please 2 label the core and the cover? 3 A. Yes, I did. 4 Q. Okay. 5 A. I was doing a core with three parts to represent 6 the No. 2 suture. But since it's an 0, I'm not exactly 7 sure how many yarns are made up of the core, but they're 8 all UHMWP -- 9 Q. Okay. 10 A. -- if that's acceptable. 11 Q. Okay. Yeah. Let me just take a look at it, 12 please. 13 Okay. So but other than the core, which you're 14 not quite sure of how many yarns make up the core on the 15 2-0, this outside accurately represents the cover or the 16 sheath of the Arthrex 2-0 FiberWire? 17 A. Yes. 18 Q. Okay. And as you have shown, going around the 19 cover or the sheath, the materials alternate PET, ultra 20 high molecular weight polyethylene, PET, ultra high 21 molecular weight polyethylene, et cetera? 22 A. Yes. 23 Q. Okay. Now within the sheath or the cover -- 24 Well, first could you just label the sheath and the cover 25 for me?</p>	<p style="text-align: right;">100</p> <p>1 time? Ever since Arthrex is manufacturing a 2-0 2 FiberWire, it's been using this configuration as shown in 3 121? 4 A. Yes. 5 Q. Okay. 6 A. (Witness complying). 7 Q. And I'm going to mark your drawing of Arthrex's 8 No. 2 FiberWire suture as DePuy Mitek Exhibit 122. 9 (DePuy Mitek Exhibit No. 122, drawing of Peter 10 Dreyfuss of the Approximate Cross-Section of No. 2 11 FiberWire, was marked for identification.) 12 Q. Can I take a look at it, please? 13 A. Yes. 14 Q. Okay. And so this shows a core made up of three 15 ultra high molecular weight polyethylene yarns twisted 16 together and then a cover or sheath composed of 17 alternating yarns of ultra high molecular weight 18 polyethylene and PET; is that right? 19 A. Correct. 20 Q. And the PET and ultra high molecular weight 21 polyethylene that make up the sheath or cover of Arthrex's 22 FiberWire No. 2 are in direct contact with each other; is 23 that right? 24 A. Yes. 25 Q. Okay. And they're intertwined around each other;</p>
<p style="text-align: right;">99</p> <p>1 A. (Witness complying). 2 Q. Are the individual yarns in the cover or sheath 3 of the Arthrex 2-0 FiberWire as shown in 121 in contact 4 with each other, meaning is the ultra high molecular 5 weight polyethylene yarn connected to the neighboring PET 6 yarn? 7 MR. TAMBURIO: Object to the form. 8 A. They're all interdigitated. I'm sure there's 9 contact between them. 10 Q. Intertwined? 11 A. Yes. 12 Q. Okay. So there is contact then between the 13 neighboring or adjacent PET and ultra high molecular 14 weight -- 15 A. Yes. 16 Q. -- polyethylene yarns and the sheath or cover? 17 A. Yes. 18 Q. Okay. Next, if you could, could you please draw 19 a cross-section of Arthrex's No. 2 FiberWire? 20 And -- I'm sorry. But before we go on, does 21 Exhibit 121 reflect the construction or the structure of 22 the 2-0 FiberWire as it's always been? 23 A. To the best of my knowledge, yes. 24 Q. Okay. So the construction with the structure as 25 shown in 121 of a 2-0 FiberWire suture hasn't changed over</p>	<p style="text-align: right;">101</p> <p>1 right? 2 A. They're braided. 3 Q. Okay. Is that intertwining or -- 4 A. Yes, they're ... 5 Q. Okay. And does Exhibit 122 accurately reflect 6 the construction of Arthrex's FiberWire No. 2 currently 7 and since its release or since it was first sold by 8 Arthrex? 9 MR. TAMBURIO: Object to the form. 10 A. I believe so. 11 Q. Okay. Could you mark or title Exhibit 122? 12 A. (Witness complying). 13 Q. And next I was going to ask you to draw a 14 cross-section of the No. 5 Arthrex FiberWire suture, which 15 I believe is the same as Exhibit 122 that you have just 16 drawn with the exception of possibly the number of yarns 17 that comprise the core; is that right? 18 A. I believe that would be correct. 19 Q. Okay. And -- but the outside of the cover or 20 sheath of the Arthrex FiberWire No. 2 is the same as the 21 cover or sheath of the Arthrex FiberWire No. 2; right? 22 A. In the manner of braiding, yes. 23 Q. Right. 24 MR. TAMBURIO: Object to the form. 25 Q. In the manner as you have shown in Exhibit</p>

26 (Pages 98 to 101)

<p style="text-align: right;">102</p> <p>1 No. 122?</p> <p>2 A. Yes.</p> <p>3 Q. I misspoke there, but the outside or the cover of</p> <p>4 the Arthrex FiberWire No. 5 is the same as the cover or</p> <p>5 sheath of the Arthrex FiberWire No. 2; is that correct?</p> <p>6 A. That's correct.</p> <p>7 Q. Okay. The same in terms of configuration and</p> <p>8 contact and intertwining; right?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. Next, if I can ask you to draw the</p> <p>11 cross-section of Arthrex's No. 0 FiberWire.</p> <p>12 A. Let's see.</p> <p>13 Q. And I believe you testified earlier, and correct</p> <p>14 me if I'm wrong --</p> <p>15 A. Twelve.</p> <p>16 Q. -- that there's twelve carriers?</p> <p>17 A. Correct.</p> <p>18 Q. Okay. And I also believe you testified earlier</p> <p>19 that you weren't sure about how many yarns make up the</p> <p>20 core in Arthrex's Size 0 FiberWire; is that right?</p> <p>21 A. That's correct.</p> <p>22 Q. Okay.</p> <p>23 A. I'm sorry; would you give me the number again?</p> <p>24 MR. TAMBURO: Here.</p> <p>25 A. All right.</p>	<p style="text-align: right;">104</p> <p>1 Dreyfuss of the Approximate Cross-Section of Size 3-</p> <p>2 FiberWire, was marked for identification.)</p> <p>3 Q. And just so the record's clear, all these hand</p> <p>4 drawings that you have done so far, when it says UHMW,</p> <p>5 that means ultra high molecular weight polyethylene?</p> <p>6 A. Correct.</p> <p>7 Q. Okay. And what you've shown is that Arthrex's</p> <p>8 No. 3-0 FiberWire has alternating yarns of PET and ultra</p> <p>9 high molecular weight polyethylene?</p> <p>10 A. Correct.</p> <p>11 Q. And that those neighboring yarns and the sheath</p> <p>12 or cover contact each other?</p> <p>13 A. Correct.</p> <p>14 Q. And they're in the same -- you know --</p> <p>15 intertwining manner as Exhibits 123, 122, and 121?</p> <p>16 A. Correct.</p> <p>17 Q. And now if you could just draw for me a</p> <p>18 cross-sectional drawing of Arthrex's 4-0 FiberWire suture,</p> <p>19 please. And I'm going to mark your drawing of Arthrex's</p> <p>20 4-0 FiberWire suture with DePuy Mitek Exhibit 125.</p> <p>21 A. (Witness complying).</p> <p>22 (DePuy Mitek Exhibit No. 125, drawing of Peter</p> <p>23 Dreyfuss of the Approximate Cross-Section of Size 4-</p> <p>24 FiberWire, was marked for identification.)</p> <p>25 Q. And I believe what you've shown in Exhibit 125 is</p>
<p style="text-align: right;">103</p> <p>1 Q. Now I'm going to mark your drawing of a</p> <p>2 cross-section of Arthrex's No. 0 FiberWire with DePuy</p> <p>3 Mitek Exhibit 123.</p> <p>4 (DePuy Mitek Exhibit No. 123, drawing of Peter</p> <p>5 Dreyfuss of the Approximate Cross-Section of Size 0</p> <p>6 FiberWire, was marked for identification.)</p> <p>7 Q. And I believe what you've drawn in Exhibit 123 is</p> <p>8 that the cover or sheath of the Arthrex No. 0 FiberWire</p> <p>9 has alternating yarns of PET and ultra high molecular</p> <p>10 weight polyethylene; is that right?</p> <p>11 A. Correct.</p> <p>12 Q. And that -- and that those neighboring yarns in</p> <p>13 the sheath or cover are in contact with each other?</p> <p>14 A. Correct.</p> <p>15 Q. And in the same configuration and intertwining</p> <p>16 manner as Exhibits 122 and 121?</p> <p>17 A. Correct.</p> <p>18 Q. Okay. Could you draw for me a cross-section of</p> <p>19 Arthrex's FiberWire 3-0 suture? I believe you testified</p> <p>20 earlier that it's eight carriers.</p> <p>21 A. Thank you.</p> <p>22 Q. And I'm going to label your cross-section drawing</p> <p>23 of Arthrex's FiberWire No. 3 suture with DePuy Mitek</p> <p>24 Exhibit 124.</p> <p>25 (DePuy Mitek Exhibit No. 124, drawing of Peter</p>	<p style="text-align: right;">105</p> <p>1 that, one, there's no core in the 4-0 FiberWire; right?</p> <p>2 A. Correct.</p> <p>3 Q. And that the sheath or cover is made up of</p> <p>4 intertwining yarns of ultra high molecular weight</p> <p>5 polyethylene and PET?</p> <p>6 A. Correct.</p> <p>7 Q. And that the neighboring yarns within the cover</p> <p>8 or sheath are in contact with each other?</p> <p>9 A. Correct.</p> <p>10 Q. Okay. Do Exhibits 123, 124, and 125 show not</p> <p>11 only the present-day but the configuration of the</p> <p>12 FiberWire sutures as sold in the past?</p> <p>13 A. Yes, to the best of my knowledge and --</p> <p>14 Q. In other words, there hasn't been any different</p> <p>15 configurations of Arthrex's 0, 3-0, and 4-0 FiberWire</p> <p>16 sutures?</p> <p>17 A. I'm not for certain on the 4-0.</p> <p>18 Q. Okay. But for the 2-0 and the -- or for the 0</p> <p>19 and the 3-0 you are?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And I don't think I asked you this, but in</p> <p>22 Exhibit 125, the alternating sheaths -- alternating yarns</p> <p>23 and the sheath or cover are in intertwining contact like</p> <p>24 Exhibits 124, 123, 122, and 121?</p> <p>25 A. Yes.</p>

FiberWire™

IMPORTANT PRODUCT INFORMATION WICHTIGE PRODUKTINFORMATION NOTICE D'UTILISATION IMPORTANTE IMPORTANTI INFORMAZIONI PER L'USO INSTRUCCIONES IMPORTANTES PARA EL USO

CE 0086



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DFU-0085
Rev. 5

Description:

Arthrex FiberWire is available in several U.S.P. sizes (sutures meet U.S.P. standards for suture, except diameter). The Arthrex FiberWire may also be sold with needles attached (swaged) to the ends in a variety of sizes. The suture is made of polyethylene fibers and polyester fibers braided, sterilized and coated for surgical use. The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue. The Arthrex FiberWire is available non-dyed (white) or dyed and meets or exceeds U.S.P. and European standards (except for diameter).

Indications:

Arthrex FiberWire is indicated for use in soft tissue approximation and/or ligation. FiberWire is not for use in cardiac indications.

Actions:

Arthrex FiberWire, when tested per ISO/DIS 10993, *Biological Evaluation of Medical Devices-Part 10: Tests for Irritations and Sensitization*, had no reactions of allergic or sensitive nature. The dyed suture and coating are pharmacologically inactive.

Arthrex FiberWire is not absorbed, but may become encapsulated in the surrounding connective tissues. The Arthrex FiberWire is not known to have significant change in tensile strength *in vivo*.

Contraindications:

None known

Warnings:

Do not re-sterilize. Once open, discard unused suture. Do not expose to heat.

Users should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing Arthrex FiberWire for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

As with any foreign body, prolonged contact of this or any other suture with soft solutions, such as those found in the urinary or biliary tracts, may result in calculus formations. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

Precautions:

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Assure that all knots have been secured using accepted surgical knot tying techniques. Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments. Care should be taken to prevent damage to surrounding

tissue or user puncture due to improper handling of the needlepoint.

Do not grasp the needle at the point or swage, to avoid damage to these areas. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Discard used needles in "sharps" containers.

Adverse Reactions:

Adverse reactions have not been noted with the Arthrex FiberWire product in animal testing. Common non-absorbable suture reactions may include wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, enhanced bacterial infectivity, minimal acute inflammatory tissue reaction, pain, edema, and erythema at the wound site. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

Sterilization:

Arthrex FiberWire suture is supplied sterile. Method of sterilization - EO. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused sutures.

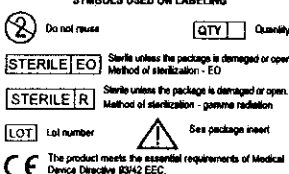
Storage Conditions:

Store below 25°C, away from moisture and direct heat. Do not use after expiration date.

How Supplied:

The Arthrex FiberWire is available in several U.S.P. sizes (sutures meet U.S.P. standards for suture, except diameter). The suture is supplied sterile in pre-cut lengths and in some cases with swaged needles. The Arthrex FiberWire is available in non-dyed (white) or dyed colors. The suture is made of polyethylene fibers and polyester fibers braided, sterilized and coated for surgical use. The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue.

SYMBOLS USED ON LABELING



Beschreibung:

Arthrex FiberWire ist in verschiedenen USP-Größen erhältlich (das Nahtmaterial entspricht den USP-Normen für Nahtmaterial, mit Ausnahme des Durchmessers). Arthrex FiberWire ist unter Umständen auch mit an den Fadenenden befestigten (gesenkgeschmiedeten) Nadeln unterschiedlicher Größen erhältlich. Das Nahtmaterial besteht aus geflochtenen, sterilisierten und für den chirurgischen Gebrauch beschichteten Polyethylen und Polyesterfäden. Die Beschichtung fungiert als Fadengleitmittel und erleichtert die Knotenbildung und das Durchziehen des Fadens durch das Gewebe. Arthrex FiberWire ist ungefärbt (weiß) oder gefärbt erhältlich und entspricht oder übertrifft USP- und europäische Standards (mit Ausnahme des Durchmessers).

Anwendungsgebiete:

Arthrex FiberWire ist für Weichgewebeanäherung und/oder -ligatur vorgesehen. FiberWire nicht für Kardi-Indikationen verwenden.

Funktionen:

Tests bei Arthrex FiberWire gemäß ISO/DIS 10993, *Biological Evaluation of Medical Devices - Part 10: Reiz- und Sensibilisierungstests* ergaben keine allergischen oder empfindlichen Reaktionen. Das gefärbte Nahtmaterial und die Beschichtung sind pharmakologisch inaktiv.

Arthrex FiberWire wird zwar nicht absorbiert, jedoch unter Umständen vom umgebenden Bindegewebe eingekapselt. Bei Arthrex FiberWire wurde *in vivo* keine signifikante Änderung der Reißfestigkeit festgestellt.

Gegenanzeigen:

Unbekannt

Warnhinweise:

Nicht resterilisieren. Unbenutztes Fadenmaterial nach dem Öffnen entsorgen. Von Hitze fernhalten.

Benutzer sollten vor dem Verschließen von Wunden mit Arthrex FiberWire mit den chirurgischen Prozeduren und Techniken vertraut sein, bei denen nicht-absorbierbarer Faden verwendet wird, da das Dehsenzrisiko je nach Anwendungsstelle und verwendetem Fadenmaterial unterschiedlich ist.

Wie bei Fremdkörpern aller Art kann der längere Kontakt dieses oder jedes anderen Fadenmaterials mit Salzlösungen (wie sie z.B. im Harn- und Gallentrakt vorhanden sind) zu Calculusbildung führen. Bei der Drainage und beim Schließen von infizierten oder kontaminierten Wunden sind die in der Chirurgie üblichen Praktiken zu beachten.

Vorsichtsmaßnahmen:

Bei der Handhabung dieses oder jedes anderen Fadenmaterials sorgfältig darauf achten, dass das Material nicht beschädigt wird. Schäden durch Zusammendrücken oder Abklemmen mit chirurgischen Instrumenten wie Zangen oder Nadelhaltern nach Möglichkeit vermeiden.

Sicherstellen, dass sämtliche Knoten gemäß den akzeptierten chirurgischen Knotenbildungstechniken sicher befestigt wurden. Voraussetzung für angemessene Knotenhaltbarkeit ist die Verwendung von flachen, quadratischen Schleifen mit zusätzlichen Verknüpfungen, je nach chirurgischer Situation und Erfahrung des

Chirurgen. Besonders beim Verknüpfen von monofilamenten Fäden sind unter Umständen zusätzliche Verknüpfungen angebracht. Sorgfältig vorgehen, um Schäden an umgebenden Gewebe und Benutzerpunktionierung durch falsche Handhabung der Nadelspitze zu vermeiden.

Die Nadel nicht an der Spitze oder am Gesenk festhalten, um eine Beschädigung dieser Bereiche zu vermeiden. Nadeln können durch Umformen an Stärke verlieren und gegen Verbiegen und Abbrechen weniger widerstandsfähig werden. Nadeln in entsprechend gekennzeichneten Behältern entsorgen.

Nebenwirkungen:

Bei Tierversuchen wurden bei der Verwendung von Arthrex FiberWire keine Nebenwirkungen festgestellt. Bei nicht-absorbierbarem Faden üblichen Reaktionen unter Umständen Dehsenz, Calculusbildung, Harn- und Gallenwegen bei längerem Kontakt mit Salzlösungen (wie sie im Urin und in der Gallenflüssigkeit vorhanden sind), verstärkte Bakterieninfektion, minimale akute Gewebeerkrankungen, Schmerzen, Ödeme und Erythema an der Wundstelle. Versaherliches Stechen mit kontaminierten chirurgischen Nadeln kann zur Übertragung von Blutpathogenen führen.

Sterilisation:

Arthrex FiberWire wird steril geliefert. Sterilisationsmethode - EO. Nicht resterilisieren. Bei beschädigter oder zuvor geöffnete Packung nicht verwenden. Offenes, unbenutztes Fadenmaterial entsorgen.

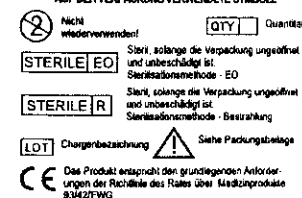
Lagerungsbedingungen:

Unter 25 °C trocken und fern von direkter Hitzeeinwirkung lagern. Nicht nach dem Verfallsdatum verwenden.

Lieferform:

Arthrex FiberWire ist in verschiedenen USP-Größen erhältlich (das Nahtmaterial entspricht den USP-Normen für Nahtmaterial, mit Ausnahme des Durchmessers). Das Fadenmaterial wird steril in vorgeschrittenen Längen und in manchen Fällen mit gesenkgeschmiedeten Nadeln geliefert. Arthrex FiberWire ist ungefärbt (weiß) und gefärbt erhältlich. Das Nahtmaterial besteht aus geflochtenen, sterilisierten und für den chirurgischen Gebrauch beschichteten Polyethylen und Polyesterfäden. Die Beschichtung fungiert als Fadengleitmittel und erleichtert die Knotenbildung und das Durchziehen des Fadens durch das Gewebe.

AUF DER VERPACKUNG VERWENDETE SYMBOLE



Verwendbar bis Jahr und Monat

FRANCE

Description:

La suture Arthrex FiberWire existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Arthrex FiberWire est également commercialisée avec des aiguilles séries de différentes tailles. Cette suture se compose de fibres de polyéthylène et de fibres de polyester tressées, stérilisées et traitées en surface pour les applications chirurgicales. Ce revêtement joue le rôle de lubrifiant pour faciliter le glissement du fil, le serrage des nœuds et le passage du fil à travers les tissus. La suture Arthrex FiberWire est disponible en blanc (non teinté) ou teintée, et elle est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Indications:

La suture Arthrex FiberWire est indiquée pour la ligature et le rapprochement des tissus mous. La suture Arthrex FiberWire n'est pas indiquée pour la chirurgie cardiaque.

Réactions:

Aucune réaction allergique ou sensible n'a été observée lors de la soumission de la suture Arthrex FiberWire au test exigé par la norme ISO/DIS 10993 / *Evaluation biologique des dispositifs médicaux, Partie 10: Essais d'irritation et de sensibilisation*. La suture teintée et le traitement en surface de la suture sont pharmacologiquement inactifs.

La suture Arthrex FiberWire est non résorbable. Elle peut cependant être encapsulée par le tissu conjonctif. Selon les données disponibles, la résistance à la traction de la suture Arthrex FiberWire ne change pas de manière significative in vivo.

Contre-indications:

Aucune contre-indication connue.

Précautions d'emploi:

Ne pas stériliser à nouveau. Jeter toute suture non utilisée dont l'emballage a été ouvert. Ne pas exposer à la chaleur.

Tout praticien suturant une plaie avec la suture Arthrex FiberWire doit être familiarisé aux techniques chirurgicales recommandées pour les matériaux non résorbables, car le risque de déhiscence de la plaie varie selon le site de l'intervention et selon le type de suture employé.

Comme avec tout matériau exogène, un contact prolongé de cette suture ou de tout autre fil avec un fluide salin, comme ceux circulant dans les voies urinaires ou biliaires, peut conduire à la formation de calculs. Le praticien devra respecter les règles chirurgicales relatives au drainage et à la fermeture de plaies infectées ou contaminées.

Précautions d'emploi:

Comme avec toute autre suture, éviter d'abîmer le fil lors de sa manipulation. Ne pas brasser le fil avec des instruments chirurgicaux comme une pince ou un porte-aiguille.

Réaliser tous les nœuds conformément aux techniques chirurgicales en vigueur. Opérer pour le nœud plat, qui garantit une bonne adhérence et qui est largement utilisé, avec boucles supplémentaires en fonction du cas chirurgical et de l'expérience du praticien. Si le fil est monofilament, prévoir des boucles supplémentaires pour les nœuds.

Bien contrôler la pointe de l'aiguille pour éviter de piquer les tissus environnants ou de blesser le praticien.

Ne pas saisir l'aiguille par sa pointe ou par son attache sur le fil pour éviter de l'endommager. Éviter de modifier la courbure des aiguilles pour ne pas réduire leur résistance à la déformation et à la rupture. Après usage, jeter les aiguilles dans un récipient spécial pour objets pointus et tranchants.

Effets indésirables:

Aucun effet indésirable particulier n'a été observé lors des tests du fil Arthrex FiberWire chez l'animal. Comme avec les autres fils de suture non résorbables, les réactions suivantes sont possibles : déhiscence de la plaie, formation de calculs dans les voies urinaires ou biliaires si contact prolongé avec des fluides salins comme l'urine ou la bile, infectivité bactérienne accrue, inflammation tissulaire minime, douleur, œdème et érythème au niveau de la plaie. Toute blessure avec une aiguille chirurgicale contaminée peut transmettre des germes pathogènes présents dans le sang.

Stérilisation:

La suture Arthrex FiberWire est livrée stérile.

Méthode de stérilisation : oxyde d'éthylène

Ne pas stériliser à nouveau. Ne pas utiliser si l'emballage est ouvert ou endommagé. Jeter les sutures non utilisées si leur emballage est ouvert.

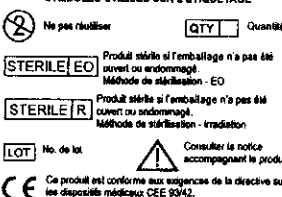
Conditions de stockage:

Conserver à une température maximale de 25°C et à l'abri de l'humidité comme des sources de chaleur directes. Ne pas utiliser après la date d'expiration.

Présentation:

La suture Arthrex FiberWire existe en plusieurs tailles U.S.P. et elle est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture est livrée stérile en différentes longueurs précoupées. Elle est aussi disponible avec des aiguilles séries. La suture Arthrex FiberWire est disponible en blanc (non teinté) ou en couleurs (teinté). Cette suture se compose de fibres de polyéthylène et de fibres de polyester tressées, stérilisées et traitées en surface pour les applications chirurgicales. Ce revêtement joue le rôle de lubrifiant pour faciliter le glissement du fil, le serrage des nœuds et le passage du fil à travers les tissus.

SYMBOLS UTILISÉS SUR L'ÉTIQUETAGE



ITALY

Descrizione:

FiberWire Arthrex è disponibile in molte misure U.S.P. (le suture soddisfano gli standard U.S.P. per sutura, tranne il diametro). FiberWire Arthrex può essere venduto anche con aghi di varie dimensioni attaccati (saldata) alle estremità. La sutura consiste in maglie di fibre di polietilene e di poliestere sterilizzate e rivestite per uso chirurgico. Il rivestimento funge da lubrificante per lo scorrimento della sutura, la chiusura dei nodi e la facilità di passaggio della sutura attraverso il tessuto. FiberWire Arthrex è disponibile sia non tinto (bianco) che tinto e soddisfa o supera gli standard U.S.P. ed europei (non per diametro).

Indicazioni:

FiberWire Arthrex è indicato per l'approssimazione e/o la legatura dei tessuti molli. FiberWire non va utilizzato in interventi cardiaci.

Azioni:

FiberWire Arthrex, quando testato per ISO/DIS 10993, *Valutazione biologica dei dispositivi medici-Parte 10: I test per irritazioni e sensibilizzazione*, non hanno evidenziato reazioni allergiche o ipersensibilità. La sutura e il rivestimento tinti sono farmacologicamente inattivi.

FiberWire Arthrex non viene assorbito, ma può essere incapsulato nei tessuti connettivi circostanti. Non sono noti per FiberWire Arthrex cambiamenti significativi nella resistenza alla tensione in-vivo.

Controindicazioni:

Nessuna nota

Avvertenze:

Non sterilizzare. Una volta aperte, gettare le suture non utilizzate. Non esporre al calore.

Gli utenti devono conoscere bene le procedure e le tecniche chirurgiche relative alle suture non assorbibili prima di utilizzare FiberWire Arthrex per la chiusura delle ferite, in quanto il rischio di deiscenza della ferita può variare in base al sito di applicazione ed al materiale utilizzato per la sutura.

Come per qualsiasi corpo estraneo, il contatto prolungato di questa e qualsiasi altra sutura con soluzioni saline, come quelle presenti nel tratto urinario o biliare, può risultare nella formazione di calcoli. È necessario seguire una pratica chirurgica corretta per il drenaggio e la chiusura di ferite infette o contaminate.

Precauzioni:

Nel trattare questo o qualsiasi altro materiale per sutura, occorre fare attenzione ad evitare danni dovuti al maneggiamento. Evitare danni da schiacciamento o piegature dovuti all'applicazione di strumenti chirurgici, inclusi forcipi o porta-aghi.

Assicurarsi che tutti i nodi siano stati legati usando le tecniche chirurgiche di annodatura accettate. Una sicurezza adeguata del nodo richiede la tecnica chirurgica accettata di legature piatte e quadrate, nonché di ulteriori avvolgimenti in base al caso chirurgico e

all'esperienza del chirurgo. L'uso di avvolgimenti aggiuntivi può essere particolarmente appropriato per l'annodamento di monofilamenti. Evitare di recare danni al tessuto circostante o alla puntina dovuti ad una manipolazione non corretta della punta dell'ago.

Non afferrare l'ago per la punta o dalla saldatura, onde evitare danni a queste aree. Il riadattamento degli aghi può indebolirli e renderli meno resistenti alle piegature ed alle rotture. Gettare gli aghi usati in contenitori per materiale «afilati».

Effetti indesiderati:

Non si sono riscontrati effetti indesiderati con l'uso del prodotto FiberWire Arthrex nei test sugli animali. Le reazioni comuni alle suture non assorbibili possono includere la deiscenza della ferita, la formazione di calcoli nei tratti urinario e biliare dovuti al contatto prolungato con soluzioni saline come urina e bile, infettività batterica elevata, minima reazione del tessuto alle infiammazioni acute, dolore, edema ed eritema al sito della ferita. Il contatto involontario dell'ago con aghi chirurgici contaminati può risultare nella trasmissione di patogeni veicolati dal sangue.

Sterilizzazione:

La suture FiberWire Arthrex viene fornita sterile.

Metodo di sterilizzazione - EO

Non sterilizzare. Non utilizzare se la confezione è aperta o danneggiata. Gettare le suture aperte non utilizzate.

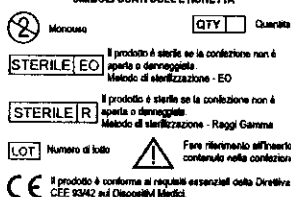
Condizioni di conservazione:

Conservare al di sotto di 25°C, lontano da umidità e calore diretto. Non utilizzare dopo la data di scadenza.

Come si presenta:

FiberWire Arthrex è disponibile in molte misure U.S.P. (le suture soddisfano gli standard U.S.P. per sutura, tranne il diametro). La sutura viene fornita sterile in lunghezze pretagliate ed in alcuni casi con aghi saldati. FiberWire Arthrex è disponibile tinto o non tinto (bianco). La sutura consiste in maglie di fibre di polietilene e di poliestere sterilizzate e rivestite per uso chirurgico. Il rivestimento funge da lubrificante per lo scorrimento della sutura, la chiusura dei nodi e la facilità di passaggio della sutura attraverso il tessuto.

SYMBOLI USATI SULL'ETICHETTA



EUROPE

Descripción:

La suture FiberWire de Arthrex viene en varios tamaños aprobados por U.S.P. (las suturas cumplen las normas de U.S.P. para suturas, excepto en el diámetro). También es posible encontrar la suture FiberWire de Arthrex en diversos tamaños y con agujas incorporadas (enhebradas) en los extremos. La sutura está hecha de fibras de polietileno y poliester trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, alar los nudos y facilitar el paso de la sutura a través del tejido. La suture FiberWire de Arthrex viene en modelos sin teñir (blanca) o teñida y cumple o supera las normas de U.S.P. y Europa (excepto en el diámetro).

Indicaciones:

La suture FiberWire de Arthrex está indicada para aplicaciones de aproximación y ligadura de tejido blando. La suture FiberWire no está indicada para uso cardíaco.

Acciones:

La suture FiberWire de Arthrex, sometida a prueba de acuerdo con la norma ISO/DIS 10993, *Evaluación Biológica de Dispositivos Médicos-Sección 10: En pruebas para detección de irritaciones y sensibilidad*, no hubo reacciones alérgicas ni de sensibilidad. La suture teñida y el recubrimiento son inactivos farmacológicamente.

La suture FiberWire de Arthrex no se absorbe, pero podría encapsularse en los tejidos conjuntivos adyacentes. La suture FiberWire de Arthrex no presenta cambios significativos conocidos en cuanto a resistencia a la tracción in vivo.

Contraindicaciones:

Ninguna conocida

Advertencias:

No esterilizar de nuevo. Una vez abierto el paquete, desechar la suture no utilizada. No exponer al calor.

Los usuarios deberán conocer los procedimientos quirúrgicos y las técnicas con suturas no absorbibles antes de utilizar FiberWire de Arthrex para cerrar heridas, ya que el riesgo de dehiscencia de las heridas varía según el sitio de aplicación y el material de suture utilizado.

Al igual que ocurre con todo cuerpo extraño, el contacto prolongado de esta suture, o de cualquier otro tipo de suture, con soluciones salinas como las halladas en los tractos urinario o biliar, podría producir cálculos. Se deben usar métodos quirúrgicos aceptables en relación con el drenaje y cierre de heridas infectadas o contaminadas.

Precauciones:

Se debe tener cuidado al manipular este o cualquier otro material de suture para evitar dañarlo. No utilice instrumentos quirúrgicos o de aplicación tales como forcéps o porta-agujas para evitar aplastar o plegar el material.

Cerciórese de que todos los nudos se hayan fijado por medio de técnicas aceptadas para nudos quirúrgicos. Para la fijación correcta de los nudos es necesario utilizar la técnica quirúrgica aceptada de nudos planos y cuadrados con lazadas adicionales, según lo requieran las condiciones quirúrgicas y la experiencia del cirujano. El uso de lazadas adicionales podría ser especialmente

útil en la elaboración de nudos de monofilamentos. Debe tenerse cuidado para evitar daños al tejido adyacente o punciones producidas por el usuario al manipular incorrectamente la punta de la aguja.

No sujete la aguja por la punta ni por el ojo para evitar daños en esas partes. Si se modifica la forma de las agujas, éstas podrían perder su firmeza y ser menos resistentes a las curvaturas y el rompimiento. Deseche las agujas usadas en recipientes para objetos punzantes.

Reacciones adversas:

No se han detectado reacciones adversas del producto FiberWire de Arthrex en pruebas con animales. Entre las reacciones comunes de las suturas no absorbibles se encuentran: dehiscencia de las heridas, formación de cálculos en los tractos urinario y biliar en condico contacto prolongado con soluciones salinas tales como la orina y la bile, mayor propensión a infecciones bacterianas, reacción mínima inflamatoria aguda del tejido, dolor, edema y eritema en el sitio de la herida. El pinchazo accidental con agujas quirúrgicas usadas podría causar la transmisión de patógenos a través de la sangre.

Esterilización:

La suture FiberWire de Arthrex se suministra estéril. Método de esterilización - EO
No esterilizar de nuevo. No utilizar si el paquete llega abierto o dañado. Desechar las suturas abiertas que no se hayan utilizado.

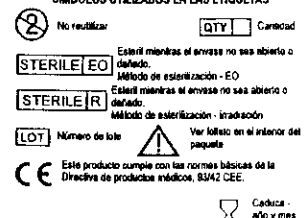
Condiciones de almacenamiento:

Almacenar el producto por debajo de 25°C, alejado de la humedad y el calor directo. No utilizar después de la fecha de caducidad.

Presentación:

La suture FiberWire de Arthrex viene en varios tamaños aprobados por U.S.P. (las suturas cumplen las normas U.S.P. para suture, excepto en el diámetro). La suture se suministra estéril en cortes de longitud predeterminada y en algunos casos con agujas enhebradas. La suture FiberWire de Arthrex se encuentra disponible en modelos sin teñir (blanca) o teñida. La suture está hecha de fibras de polietileno y poliester trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la suture, alar los nudos y facilitar el paso de la suture a través del tejido.

SYMBOLS UTILIZADOS EN LAS ETIQUETAS



IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC., a)
Massachusetts corporation,)
Plaintiff,) Civil Action
vs.) 04-12457 PBS
ARTHREX, INC., a Delaware)
corporation,)
Defendant.)

- - - - -
The deposition of DEBI PRASAD

MUKHERJEE was taken on Tuesday, June 13,
2006, commencing at 9:08 a.m., at the
offices of Dickstein Shapiro Morin &
Oshinsky LLP, 2101 L Street, N.W.,
Washington, D.C., before Susanne Bergling,
Registered Merit Reporter and Notary Public.

<p>358</p> <p>1 why the inventors should be precluded from 2 covering coated sutures with their patent? 3 A. No, I don't have any opinion. 4 Q. Okay. Do you have patents? 5 A. Yes. 6 Q. Okay. And in your patents, do you list 7 things that are claimed? 8 A. In my patent, yes, I do. 9 Q. Okay. Do you describe things in your 10 patents that may or may not be included within the 11 invention, in the description of the invention? 12 A. I don't remember what my -- I don't have 13 the patent in front of me. 14 Q. Well, in the claims, do you list every 15 possible feature of the invention? 16 MR. TAMBURIO: Objection, vague. 17 THE WITNESS: I tried to. 18 BY MR. BONELLA: 19 Q. But do you list -- don't you try to get as 20 broad a claim as you can to cover as broad a 21 concept of your invention? 22 MR. TAMBURIO: Objection, vague. He's not a 23 patent attorney. 24 THE WITNESS: I write what I -- my 25 invention is, and patent attorney actually</p>	<p>360</p> <p>1 invention, don't you want to try to protect as 2 broadly as possible? 3 A. Again, I may want something, but patent 4 attorney might come out with something different, 5 and Patent Office may come out with another 6 determination. 7 Q. If there's things in your patent that you 8 say may or may not be included within your 9 invention, but they're not listed in the claims, 10 do you think they should be excluded from the 11 claims in your patent? 12 MR. TAMBURIO: Objection, calls for a legal 13 conclusion of a patent that we're not even -- that 14 we don't have in front of us and asking him to 15 interpret claim language of a patent we don't have 16 in front of us. This is ridiculous. 17 THE WITNESS: It's so hypothetical, I 18 cannot answer that question. 19 BY MR. BONELLA: 20 Q. You cannot answer it? 21 A. No. 22 Q. Okay. Do you see in the claim, claim 1 -- 23 A. Uh-huh. 24 Q. -- it says, "A surgical suture consisting 25 essentially of a heterogenous braid," do you see</p>
<p>359</p> <p>1 formalize all of this. 2 BY MR. BONELLA: 3 Q. Okay. And -- 4 A. So, I cannot say anything more than that. 5 Q. You didn't want the broadest protection 6 possible on your patents? 7 A. Whatever the patent attorney wants -- 8 MR. TAMBURIO: Objection, misrepresents the 9 testimony. Give me a chance to object, Debi. 10 BY MR. BONELLA: 11 Q. But the patent attorney does? 12 A. Yes. 13 Q. Okay. So, it's not what you want in your 14 patents; it's what the patent attorney wants in 15 terms of protection? 16 A. Well, I provide the information, it's a 17 back and forth -- 18 Q. Right. 19 A. -- and I might say, well, it should be 20 included in this, but patent attorney is the final 21 one -- 22 Q. Right. 23 A. -- who decides on the claims and the 24 writing part of the -- as you know. 25 Q. Right. And isn't it the goal with your</p>	<p>361</p> <p>1 that? 2 A. Yes. 3 Q. Is FiberWire a surgical suture? 4 A. FiberWire is a surgical suture, yes. 5 Q. Does FiberWire consist essentially of a 6 heterogenous braid? 7 A. Yes. 8 Q. Is FiberWire composed of a first and second 9 set of continuous and discrete yarns in a 10 sterilized, braided construction wherein at least 11 one yarn from the first set is in direct 12 intertwining contact with a yarn from the second 13 set? 14 A. Their construction is quite different from 15 this described here for FiberWire, what I know of 16 FiberWire. 17 Q. Well, FiberWire has a heterogenous -- has a 18 sheath that's a braid of ultra high molecular 19 weight polyethylene and PET, right? 20 A. Sheath of those two materials, yes. 21 Q. Braided together. 22 A. Right. 23 Q. Okay. Well, is that sheath of FiberWire, 24 is that a heterogenous braid? 25 A. Yeah, they are two different materials.</p>

<p style="text-align: right;">362</p> <p>1 Q. Okay. And is the FiberWire heterogenous 2 braid composed of a first and second set of 3 continuous and discrete yarns? 4 A. Yes. 5 Q. Okay. And is the FiberWire heterogenous 6 sheath braid composed of discrete yarns in a 7 sterilized braided construction? 8 A. Yes. 9 Q. And does the FiberWire heterogenous braided 10 sheath have a braided construction where at least 11 one yarn from the first set is in direct 12 intertwining contact with a yarn from the second 13 set? 14 A. There is intertwining contact, yes. 15 Q. Okay. And in the next column, it says, 16 "Each yarn from the first set is composed of a 17 plurality of filaments of a first fiber-forming 18 material selected from the group consisting of 19 PTFE, FEP, PFA, PVDF, PETFE, PP and PE." 20 Do you see that? 21 A. I see it. 22 Q. Does the FiberWire sheath have a yarn that 23 meets that criteria? 24 A. No. 25 Q. Why?</p>	<p style="text-align: right;">364</p> <p>1 A. But that's -- the -- the FiberWire has 2 ultra high molecular weight polyethylene core. 3 Q. Right. 4 A. Yes. 5 Q. If the Court says that PE, as used in the 6 claims of the '446 patent, means ultra high 7 molecular weight polyethylene, does FiberWire meet 8 that clause (a) in column 9 of claim 1? 9 A. That's a hypothetical question. I cannot 10 answer that. 11 Q. You can't answer it? 12 A. No. 13 Q. You can't provide an opinion one way or the 14 other? 15 A. No. 16 Q. Okay. Claim 2, it says, "The surgical 17 suture of claim 1 wherein the suture is attached 18 to a needle." 19 Do you see that? 20 A. Yes. 21 Q. Is FiberWire sold attached to a needle? 22 A. Yes. 23 Q. Okay. 24 A. Not always, but I have seen the suture -- a 25 needle with -- I mean a suture with a needle.</p>
<p style="text-align: right;">363</p> <p>1 A. Because it has ultra high molecular weight 2 polyethylene for its strength, and this PE does 3 not include that ultra high molecular weight 4 polyethylene. 5 Q. And that's your opinion? 6 A. Yes. 7 Q. Okay. And the next part says, "Each yarn 8 from the second set is composed of a plurality of 9 filaments of a second fiber-forming material 10 selected from the group of PET, nylon and aramid." 11 Do you see that? 12 A. Yes. 13 Q. Does FiberWire meet that criteria? 14 A. It has the PET in it. 15 Q. So, it meets that criteria? 16 A. Uh-huh. 17 Q. And then it says, "Optionally a core." 18 FiberWire optionally has a core, right? 19 A. Right. 20 Q. Okay. If the Court defines PE, as used in 21 that claim, to mean ultra high molecular weight 22 polyethylene, if the Court defines PE to mean 23 ultra high molecular weight polyethylene -- 24 A. Not in this patent. 25 Q. No, if the Court --</p>	<p style="text-align: right;">365</p> <p>1 Q. Okay, claim 8 says, "The surgical suture of 2 claim 1 wherein the second set of yarns is PET." 3 FiberWire meets that criteria, right? 4 A. Yes. 5 Q. Claim 9 says, "The surgical suture of claim 6 8 wherein the volume fraction of the first set of 7 yarns in the braided sheath and core ranges from 8 about 20 to about 80 percent." 9 Do you see that? 10 A. I don't know at what percentage of PET and 11 the ultra high molecular weight polyethylene is in 12 the FiberWire. 13 Q. So, you don't have an opinion whether 14 FiberWire meets that limitation? 15 A. No. 16 Q. Then in claim 12, it says, "The surgical 17 suture of claim 8 wherein the suture is attached 18 to the needle." 19 Do you see that? 20 A. Yes. 21 Q. FiberWire meets -- when FiberWire is sold 22 attached to a needle, it meets that limitation? 23 A. Most of the time, but there is another 24 non-needle part, too. 25 Q. Okay. You reviewed the prosecution history</p>

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.,)	
a Private Limited Company)	
of the United Kingdom,)	
)	
Defendants.)	

Expert Report of Dr. David Brookstein

I. Background Information

A. Teaching Experience

1. I am the Dean and Professor of Engineering at the School of Engineering and Textiles of Philadelphia University. I have held this position since 1994. In 2005, I also was appointed Executive Director of Research at Philadelphia University.

2. I was a Visiting Scholar at the Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences) between 2002-2003.

3. I was an Adjunct Professor in Mechanical Engineering at Northeastern University in Boston, MA from 1981-1983. At Northeastern, I taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

4. I was Assistant Professor of Textile Engineering at Georgia Institute of Technology, College of Engineering from 1975 – 1980. At Georgia Tech, I taught and

conducted research in the fields of textile and composites engineering with special emphasis on improving the energy efficiency of manufacturing systems.

B. Work Experience

5. From 1980 to 1994, I worked at Albany International Research Co. At Albany International Research, I was an Associate Director from 1992 to 1994. From 1983 to 1992, I was an Assistant Director. From 1980 to 1982, I was a Senior Research Associate. While at Albany International Research Co., I directed all activities of the professional engineering group and was responsible for contract research, development, and manufacture of advanced composite materials and technical polymeric materials. My accomplishments include the invention and development of the multilayer interlock braiding system for producing three-dimensionally reinforced fibrous performs for aerospace structures, the development of implantable biomedical devices such as vascular prostheses and orthopedic implants and the development of unique textile-based civil engineering structures.

C. Publications

6. My publications include, among other things:

"Joining Methods of Advanced Braided Composites," Composite Structures, 6, p. 87-95, 1986.

"Structural Applications of Advanced Braided Composites," Proceedings of the SPE Advanced Polymers Composites Division, November 1988.

"Processing Advanced Braided Composite Structures," Proceedings of the WAM of ASME, Materials Division, November 1988.

"Interlocked Fiber Architecture: Braided and Woven," Proceedings of the 35th SAMPE Meeting, April, 1990.

"Evolution of Fabric Preforms for Composites," Journal of Applied Polymer Science: Applied Polymer Symposium, 47, p. 487-500, 1991.

"A Comparison of Multilayer Interlocked Braided Composites with Other 3-D Braided Composites," 3rd International Techtextil Symposium, 14-16, May 1991, Frankfurt.

"On the Mechanical Behavior of 3-D Multilayer Interlock Braided Composites," with Preller, T., and Brandt, J., DASA-Deutsche Aerospace, Proceedings of NASA Fiber-Tex '92.

"The Solid Section Multilayer Interlock Braiding System," 4th International Techtextil Symposium, 4 June 1992, Frankfurt.

"On the Mechanical Properties of Three-Dimensional Multilayer Interlock Braided Composites," TECHTEXTIL Symposium, 1993, Frankfurt.

"3-D Braided Composites-Design and Applications," Sixth European Conference on Composite Materials, 20-24 September 1993, Bordeaux.

"Concurrent Engineering of 3-D Textile Preforms for Composites," International Journal of Materials and Product Technology, Vol. 9, Nos. 1/2/3, 1994.

"Physical Properties of Twisted Structures" with Ning Pan, Fiber Society Symposium, Asheville, NC, 1998.

D. Patents

7. I am an inventor on the following U.S. Patents:

U.S. Patent 4,290,170 - "Device for Aligning and Attenuating Fiber Mats," A device for producing aligned carbon fiber webs for use in composites.

U.S. Patent 4,497,866 - "Sucker Rod," An elliptical cross-section braided composite rod for pumping oil.

U.S. Patent 4,602,892 - "Sucker Rod," A braided composite rod and coupling for pumping oil.

U.S. Patent 4,841,613 - "Pressure Developer or Press Roll Containing Composite Material," A composite press roll with variation of radial stiffness.

U.S. Patent 4,909,127 - "Braiders," A braider with non-circular braider tracks and a unique package carrier for use with braider.

U.S. Patent 5,004,474 - "Prosthetic Anterior Cruciate Ligament Design," An artificial ligament device having a tubular woven ligament and being adapted for joining the ends of two bones.

U.S. Patent 5,357,839 - "Solid Braid Structure" A 3-D system for producing braids.

U.S. Patent 5,358,758 - "Structural Member" A fiber reinforced structural member produced from a complex woven fabric.

U.S. Patent 5,411,463 - "Composite Roll and Method of Making" A fiber reinforced roll for papermaking.

U.S. Patent 5,501,133 - "Apparatus for Making a Braid Structure" A novel manufacturing system for producing 3-D multilayer interlock braided textile and fiber reinforced composite structures.

U.S. Patent 5,697,969 - "Vascular Prosthesis and Method for Implanting" A fibrous synthetic vascular graft with a combination of resorbable and non-resorbable layers.

E. Education

8. I have a Doctor of Science in the field of Mechanical Engineering, Minor Studies in Management from Sloan School of Management, Massachusetts Institute of Technology, 1976.

9. I have a Master of Science in Textile Technology from M.I.T., 1973.

10. I also hold a Bachelor of Textile Engineering, from Georgia Tech, 1971.

11. I also attended the Harvard Business School Summer Program on Research Management in 1990 and the Harvard Graduate School of Education MLE Summer Program, 1998.

12. When I was a researcher at Albany International Research Co., in the late 1980's, I led a program that involved the development of braided sutures for a commercial client. While at Albany, I researched, developed, tested and evaluated numerous braided and woven biomedical implants, including woven ACL prosthesis, braided artificial arteries, and textile-based, resorbable bone plates and screws. Furthermore, I have taught textile engineers at the undergraduate and graduate level at Philadelphia University materials that involve the design, construction, braiding, manufacturing, and processing of textile structures that includes braids. Specifically, among other things, I have taught courses in Fiber Science which include fiber and yarn tensile, bending, and compression properties. Additionally, I was awarded the TechTextil Innovation Prize (Germany) in 1993 for my work in braiding.

13. A copy of my CV is attached under Tab A. A list of my publications and patents are set forth in my CV. Over the past four years, I have been deposed or testified as an Expert Witness in five cases. A complete list of cases in which I have provided testimony within the past four years is attached under Tab B. A list of the documents that I used in forming my opinions is set forth in Tab C.

14. I have been engaged by counsel of DePuy Mitek as a consultant in this litigation at a consulting rate of \$300/hour.

II. Summary of Opinions

15. It is my opinion that sales of Arthrex's FiberWire™ and TigerWire™ suture products (in all sizes and regardless of whether it is attached to needle, or any other component)

literally infringe claims 1, 2, 8, 9, and 12 of U.S. Patent No. 5,314,446 (the '446 Patent) (Tab D). I understand that Arthrex sells FiberWire™ in the United States as free strands, attached to needles of various sizes, and attached to anchors used in various surgical applications (*e.g.*, rotator cuff repair, shoulder instability procedures). I further understand that Arthrex sells TigerWire™ in the United States attached to needles and anchors. I use the term "FiberWire™ suture products" to refer to all FiberWire™ products regardless of whether they are free strands, attached to needles, or attached to anchors. I use the term "TigerWire™ suture products" to refer to all TigerWire™ products regardless of whether they are sold attached to anchors or needles.

16. It is my opinion that sale of Arthrex's FiberWire™ and TigerWire™ suture products (in all suture sizes) directly infringes claims 1, 2, 8, 9, and 12 of the '446 Patent under the doctrine of equivalents.

17. I understand that Pearsalls imports into, and sells in, the United States unsterile, untipped FiberWire™ and TigerWire™. It is my opinion that such unsterile, untipped products are a component of the invention claimed in the '446 patent and constitute a material part of the invention claimed in claims 1, 2, 8, 9, and 12 of the '446 patent.

18. It is my opinion that the FiberWire™ and TigerWire™ sutures imported and sold by Pearsalls are especially adapted for use in infringement of claims 1, 2, 8, 9, and 12 of the 446 Patent, and are not a staple article or commodity of commerce suitable for substantial noninfringing use.

19. It is my opinion that some of the benefits of FiberWire™ and TigerWire™ sutures are due to the invention, claimed in claims 1, 2, 8, 9, and 12 of the 446 Patent.

III. Materials Considered in Forming My Opinions

20. I understand that Arthrex has admitted that Pearsalls manufactures the Arthrex FiberWire™ and TigerWire™ suture. (Arthrex's Response to Mitek Interrogatory #2). I

attended the Pearsalls plant inspection and deposition in Taunton, Somerset, England on January 11, 2006. Mr. Brian Hallet testified on behalf of Pearsalls. While attending the Pearsalls plant inspection, I personally observed the manufacturing processes used to make the braid that comprises the FiberWire™ and TigerWire™ sutures. I may testify about the manufacturing process that I observed on January 11, 2006 at Pearsalls and the explanation of it as set forth by Pearsalls at depositions and in documents. I may use videotape deposition testimony or exhibits made from the videotape to aid me in testifying.

21. The manufacturing process to make the FiberWire™ and TigerWire™ suture braids that I observed includes the following steps: twisting core and sheath yarns, steam setting core and sheath, winding braider bobbins, braiding, winding to skein, scouring, dyeing, stretching, coating, and thermal treating, and subsequent inspection. I also observed Pearsall's testing laboratory. I may testify about each of these processes and the Pearsalls' equipment used in the manufacturing and testing processes. In addition to observing the manufacturing processes, I have also reviewed documents that describe them (DMI Exs. 279, 281, 287-312). I may rely on these documents in testifying about FiberWire™ and TigerWire™.

22. I have reviewed technical documents concerning FiberWire™'s and TigerWire™'s construction and manufacturing. I have also reviewed deposition transcripts of technical witnesses concerning FiberWire™ and TigerWire™, including the depositions of, among others, Arthrex Engineer, Peter Dreyfuss, Arthrex's Vice President of Operations Kevin Grief, and Pearsalls' Brian Hallet. A list of the documents that I used in forming my opinions is set forth in Tab C.

23. I have examined samples of FiberWire™ and samples of FiberWire™ taken at various stages of the manufacturing processes (DMI Exs. 282, 283, 284, 285, 342 and Bates nos. ARM 25451-52, and ARM 25590).

IV. Legal Framework of My Opinions

I have been told by counsel to apply the following principles of United States Patent law in my analysis.

A. Direct Infringement

24. I understand that the statutory basis for a determination of direct patent infringement is set forth in 35 U.S.C. §271(a) which states:

Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any Patented invention, within the United States or imports into the United States any Patented invention during the term of the Patent therefore, infringes the Patent.

25. I understand that an analysis of direct infringement requires two steps. First, the Court determines the meaning of the claims. Then, the properly construed claims are applied to a product to determine whether it infringes the Patent. I understand there are two types of direct infringement -- literal infringement and infringement under the doctrine of equivalents.

26. Infringement is “literal” when each claim limitation is literally present in a device. I understand that even if a device does not literally have each claim limitation, there is still infringement if the device has an equivalent of the claimed limitation that is not literally present. I understand that one method for determining whether a structure is equivalent to a claim limitation is the insubstantial differences test. Under this test, if the differences between the structure and the claim element are insubstantial, then they are equivalent. One method for determining whether the differences are insubstantial is whether the structure in the accused

device “performs substantially the same function in substantially the same way to obtain the same result” (“function/way/result test”) as the claimed element.

V. Direct Infringement

A. Claim Construction

27. As mentioned above, I understand that the first step in an infringement analysis is to construe the claims. I understand that the Court will determine the meaning of the claim terms in the ‘446 Patent. Until the Court determines the meaning of the claims, I have been asked to assume the meaning of the following claim terms.

“PE” – means all types of polyethylene (PE) including ultra high molecular weight polyethylene.

“consisting essentially of” – means the claimed suture with all of its limitations and any other unlisted materials that do not materially affect the basic and novel characteristics of the claimed suture.

I have been told that the Court will determine the basic and novel characteristics of the claimed invention. I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid.

“direct intertwining contact” –means the mechanical interlocking or weaving of the individual yarns that make up the suture braid.

“volume fraction of the first set of yarns in the braided sheath and core” means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture.

I reserve the right to modify my opinion should the Court determine the meaning of the claims are different than the above constructions provided by counsel.

B. Literal Infringement

28. I have been asked to provide my expert opinion regarding whether Arthrex's FiberWire™ and TigerWire™ suture products infringe claims 1, 2, 8, 9, and 12 of the '446 Patent. It is my opinion that Arthrex's FiberWire™ and TigerWire™ suture products infringe claims 1, 2, 8, 9, and 12 of the '446 Patent. It is my understanding that Arthrex has offered for sale or sold each of its FiberWire™ and TigerWire™ suture products within the United States. Therefore, there is literal infringement because, as described below, each of Arthrex's FiberWire™ and TigerWire™ suture products literally has all of the limitations of claims 1, 2, 8, 9, and 12. In determining literal infringement, I first consider the construction of FiberWire™ and TigerWire™. Then, I compare the claims, with the definitions as provided above, to the FiberWire™ and TigerWire™ suture products.

1. Arthrex's FiberWire™ and TigerWire™ Suture Products

29. I understand that all Arthrex's FiberWire™ suture, except size 4-0, is made of a core of polyethylene yarns (of the ultra high molecular weight type) and a braided sheath of polyethylene yarns (of the ultra high molecular weight type) and PET yarns (Dreyfuss 9/16/05 Dep. at 43, 55-57). The braided sheath is made by having one set of carriers, which have polyethylene, traversing the braider bed in a serpentine and clockwise fashion and the other set of carriers, which have PET, traversing the braider bed in a serpentine counter-clockwise fashion. I understand that Arthrex sells only sizes 5, 2, 0, 2-0, 3-0, and 4-0 FiberWire™ (Dreyfuss 9/16/05 Dep. at 31). I understand that the description of FiberWire™ is generally described in Arthrex's 510K for FiberWire™ (DMI Ex. 78 at ARM 001899).

30. I also understand that no. 2 Arthrex TigerWire™ is basically identical to no. 2 FiberWire™ with one exception. TigerWire™ has one black nylon yarn that replaces one of the PET yarns in no. 2 FiberWire™. No. 2 TigerWire™ has 8 yarns of PE, 7 yarns of PET, and 1 yarn of nylon braided together. (DMI Ex. 318) I also understand that Arthrex sells TigerWire™ in only size no. 2 (Dreyfuss 9/16/05 Dep. at 106). I understand that Arthrex also sells a TigerTail™¹ product that “is a version of FiberWire™ suture with a black strand that creates spiral marking along one-half length of the suture” (DMI Ex. 318).

31. I understand that FiberWire™ and TigerWire™ have been made with “Spectra” and “Dyneema” ultra high molecular weight polyethylene yarns in manufacturing the FiberWire™ suture (Dreyfuss Dep. p. 44-45, Grieff Dep. 9/15/05 p. 22-23, and 51). Spectra and Dyneema are trade names for certain companies’ ultra high molecular weight polyethylene.

32. Arthrex’s FiberWire™ and TigerWire™ suture is coated with NuSil Med-2174 manufactured by NuSil technology. (Dreyfuss 9/16/05 Dep. at 42). NuSil MED-2174 is generally described at DMI Ex. 78 at ARM 1933-36. I also understand that Arthrex sells a FiberStick™² product. I understand FiberStick™ to be a 50 inch piece of FiberWire™ that has 12 inches of its length stiffened with Loc-Tite (DMI Ex. 3 and Dreyfuss 9/16/05 Dep. at p. 122).

¹ Because TigerTail™ includes FiberWire™, TigerTail™ infringes the ‘446 patent for the same reasons that FiberWire™ infringes.

² Because FiberStick™ includes a portion of FiberWire™, FiberStick™ infringes the ‘446 patent for the same reasons that FiberWire™ does.

**2. Arthrex's FiberWire™ and TigerWire™ Suture Products
Literally Infringe Claim 1**

33. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products³ literally infringe claim 1 of the '446 because they literally have all of the limitations of claim 1 as set forth below.

Claim 1 of the '446 Patent	FiberWire™ and TigerWire™ Suture Products
A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and	The sterilized FiberWire™ and TigerWire™ suture is a braid of polyethylene (PE) and polyester (PET). ⁴ The PE and PET yarns are both continuous and discrete. The PE and PET are mechanically intertwined so that at least one PE yarn and one PET yarn are braided in direct intertwining contact. (DMI Ex. 318)
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The FiberWire™ and TigerWire™ suture is made from PE yarns that are made of a plurality of PE filaments. (Dreyfuss 9/16/05 Dep. at p. 50:21-51:1)

³ I understand that Arthrex's FiberWire™ and TigerWire™ suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-75SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF, AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR-1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 3). To the extent that I have not recited a specific Arthrex product by name or code, if any unrecited product includes any portion of a FiberWire™ or TigerWire™ suture, it would infringe claims 1, 2, 8, 9, and 12 of the '446 patent for the same reasons stated herein.

- ⁴ Q. And what incoming yarns are received by Pearsalls when Pearsalls manufactures and braids the bulk sutures made for Arthrex's FiberWire™ sutures?
- A. Incoming yarns would be ultra high molecular weight polyethylene and PET. (Dreyfuss 9/16/05 Dep. at p. 43:15-19)

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon, and aramid; and	The FiberWire™ and TigerWire™ suture is made from PET yarns that are made of a plurality of PET filaments. (Dreyfuss 9/16/05 Dep. at p. 64:14-17)
c) optionally a core.	Arthrex's FiberWire™ sutures have a core except for 4-0 FiberWire™. (DMI Ex. 318)

34. I understand that Arthrex has contended that it does not infringe claim 1 of the '446 Patent for several reasons. To the extent that I understand these positions, I will address them here. I reserve the right to amend or supplement my opinions based on Arthrex's full explanation of its positions.

35. I understand that Arthrex may contend that its FiberWire™ and TigerWire™ products do not infringe claim 1 because they have a coating of NuSil MED-2174. I further understand that the basis of Arthrex's argument is that the coating materially affects the basic and novel characteristics of the claimed invention. As I understand the argument, I disagree with it.

36. As explained above, I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The addition of a coating on FiberWire™ and TigerWire™ does not have any material affect on these basic and novel characteristics. Regardless of the coating, FiberWire™ and TigerWire™ both still have a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The coating

is non-bioabsorbable and does not materially affect bioabsorbability of the yarns, does not materially affect at least one yarn from the first set being in direct intertwining contact with a yarn from the second set, and the coating does not materially affect each yarn from contributing to the overall properties of the heterogeneous braid. Furthermore, Arthrex documents describe the coating as a lubricant (DMI Ex. 78 at ARM1976).

37. The '446 Patent specifically contemplates, in the "Detailed Description of the Invention," that the braided sutures of the invention can be coated (Tab D at 6:5-21). The '446 Patent describes the invention as including applying polymer coatings by making a solution of the polymer and a solvent, immersing the suture in the coating and solvent, and drying the suture (Tab D at 6:9-11). Thus, the '446 Patent's description of the invention as contemplating coatings supports my opinion that FiberWire™'s and TigerWire™'s coatings do not materially affect the novel and basic characteristics of the invention because the inventors specifically contemplated coated sutures. Notably, FiberWire™ and TigerWire™ are coated just as the '446 Patent describes; they are immersed in a solution of NuSil MED-2174 and a solvent and dried.⁵

38. Further, I have taken Scanning Electron Micrographs at the Materials Evaluation laboratory at the Philadelphia University Research Center of DMI exhibit 284 (uncoated), DMI exhibit 342 (coated once), and DMI exhibit 285 (coated twice) FiberWire™ suture braids. My Scanning Electron Micrographs are attached at Tabs E (DMI Ex. 284), F (DMI Ex. 342), G (DMI Ex. 285).

⁵ My opinion is further supported because the '446 Patent claims a "suture." I understand that most sutures are coated. Thus, the Patent claims clearly contemplate sutures having coatings, otherwise they would not cover many, if any, sutures.

39. It is my expert opinion and observation from the above Micrographs that the coating on the FiberWire™ suture does not substantially permeate the braided structure and does not reside between the braid yarns.

40. It is my expert opinion and observation that the coating only appears on the surface of the braid.

41. I understand that Arthrex may argue that its FiberWire™ and TigerWire™ suture products do not literally infringe claim 1 because generally at least one end of its FiberWire™ and TigerWire™ suture products are “tipped.” I also understand that Arthrex may argue that FiberStick™ does not infringe because about 12 of the 50 inches of its FiberStick™ product is stiffened. With respect to FiberWire™ & TigerWire™, tipping means stiffening the end of the suture with Loc-Tite. (Dreyfuss 9/16/05 Dep at p. 122). To the extent I understand Arthrex’s position, I disagree with it.

42. In my opinion, the stiffening and tipping is irrelevant because the remainder of the FiberWire™, TigerWire™, and FiberStick™ suture products are not tipped or stiffened. Thus, at least a significant length of the FiberWire™, TigerWire™ and FiberStick™ suture products infringe. Therefore, regardless of the tipping and stiffening, FiberWire™, TigerWire™, and FiberStick™ infringe for the reasons set forth above.

43. Moreover, it is generally known that multifilament sutures have tipped ends so that they do not fray. Because the claims of the ‘446 patent are directed to a multifilament suture, it would not make sense for a multifilament suture claim to eliminate almost all multifilament sutures because of such a basic characteristic, *i.e.* tipped ends.

44. As explained above, Arthrex’s TigerWire™ is substantially identical to Arthrex’s FiberWire™ except that one carrier of PET yarn is replaced with a black nylon strand.

Otherwise, Arthrex's FiberWire™ braid is no different than Arthrex's TigerWire™ braid.⁶ I understand that Arthrex contends that its TigerWire™ suture products do not infringe because they have one black nylon strand. To the extent that I understand Arthrex's argument, I disagree.

45. It is my opinion that the nylon marking strand in Arthrex's TigerWire™ suture is non-bioabsorbable and therefore does not materially affect the basic and novel characteristics of the invention in the '446 Patent. For one thing, nylon is expressly mentioned in claim 1 as one of the fiber-forming materials from which the second set yarn can be made. Thus, the inventors contemplated it as being part of their invention, not as changing the basic and novel characteristics of their invention. Further, the inclusion of nylon yarn instead of one yarn of PET (I understand that nylon makes up only 3.4% of TigerWire™ suture, DMI Ex. 318) does not materially affect the basic and novel characteristics of the invention because the braid is still a heterogeneous braid of non-bioabsorbable yarns of the type claimed, at least one yarn of PE is in direct intertwining contact with a PET yarn, and the nylon does not materially affect the yarns from contributing to the properties of the overall braided suture.

46. My opinion is supported by Mr. Dreyfuss' testimony. Mr. Dreyfuss testified on behalf of Arthrex that that the nylon in Arthrex's TigerWire™ suture products is for visual identification and has "minute differences in its feel and strength characteristics" (Dreyfuss 9/16/05 Dep. at p. 75:7-14). Since visual identification is not a basic and novel characteristic, the inclusion of a nylon marker band has no material effect on the basic and novel characteristics of the invention.

⁶ Q. Sure. Sure. Is the braid in any Arthrex TigerWire™ different than the braid used in Arthrex's No. 2 FiberWire™?

A. The braid, no. (Dreyfuss 9/16/05 Dep. at p. 31, line 24 – p. 32, line 2)

**3. Arthrex's FiberWire™ and TigerWire™ Needle Products
Literally Infringe Claim 2**

47. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ needle products⁷ literally have all of the limitations of claim 2.

Claim 2	Arthrex's FiberWire™ and TigerWire™ needle products
The surgical suture of claim 1 wherein the suture is attached to a needle.	Each FiberWire™ & TigerWire™ suture needle product has a FiberWire™ suture attached to a needle (DMI Ex. 3).

**4. Arthrex's FiberWire™ and TigerWire™ Suture Products
Literally Infringe Claim 8**

48. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products⁸ literally infringe claim 8 of the '446 for the following reasons:

Literal FiberWire™ Structure	Claim 8
The surgical suture of claim 1 wherein the second set of yarns is PET.	Each FiberWire™ and TigerWire™ suture product has PET as a second set of yarns.

⁷ Arthrex's FiberWire™ and TigerWire™ needle products includes all Arthrex's products that are sold with a needle attached to a FiberWire™ or TigerWire™ suture including at least the following Arthrex catalog product codes AR-7200, AR-7202, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7211, AR-7219, AR-7220, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1324BNF, AR-1920BNP, AR-1934BNF, AR-1920BN, AR-1920BNF, AR-1925BNF, AR-1925BNP, AR-1927BNF, AR-1928SNF, and AR-1928SNF-2 (DMI Ex. 3).

⁸ I understand that Arthrex's FiberWire™ and TigerWire™ suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF, AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR-1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 3).

(DMI Ex. 318).

**5. Arthrex's FiberWire™ and TigerWire™ Suture Products
Literally Infringe Claim 9**

49. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products⁹ literally infringe claim 9 of the '446. I have used the following definition of "volume fraction of the first set of yarns in the braided sheath and core" which means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture. For the following reasons, FiberWire™ and TigerWire™ literally infringe claim 9 of the '446 patent for the following reasons:

Claim 9	Arthrex's FiberWire™ and TigerWire™ Products
The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to 80 percent.	Every Arthrex's FiberWire™ and TigerWire™ construction has a ratio of the cross-sectional area of UHMWPE in the sheath and core to the total cross sectional area of all the yarns in the surgical suture that ranges from 20 to 80 percent. (DMI Ex. 318).

⁹ Arthrex's FiberWire™ and TigerWire™ suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-75SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF, AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR-1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 3).

6. Arthrex's FiberWire™ and TigerWire™ Needle Products Literally Infringe Claim 12

50. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ needle products¹⁰ literally have all of the limitations of claim 12.

Claim 12	Arthrex's FiberWire™ and TigerWire™ Needle Products
The surgical suture of claim 8 wherein the suture is attached to a needle.	Arthrex's FiberWire™ and TigerWire™ needle products have either a FiberWire™ or TigerWire™ suture attached to a needle. (DMI Ex. 3).

C. Arthrex's FiberWire™ and TigerWire™ Suture Products Literally Infringe Under the Doctrines of Equivalents

51. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products also infringe claims 1, 2, 8, 9, and 12 of the '446 Patent under the doctrine of equivalents because the differences, if any, between the claims, as I understand they may be construed by Arthrex, and Arthrex's FiberWire™ and TigerWire™ suture products are insubstantial.

52. I understand that Arthrex contends that there is no literal infringement because the claim limitation with respect to the "first-fiber-forming material" is not present because, although FiberWire™ has "PE" or polyethylene, it has one type of "PE," ultra high molecular weight polyethylene (UHMWPE). If it is determined that "PE" as claimed does not mean

¹⁰ Arthrex's FiberWire™ and TigerWire™ needle products includes all Arthrex's products that are sold with a needle attached to a FiberWire™ or TigerWire™ suture including at least the following Arthrex catalog product codes AR-7200, AR-7202, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7211, AR-7219, AR-7220, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1324BNF, AR-1920BNP, AR-1934BNF, AR-1920BN, AR-1920BNF, AR-1925BNF, AR-1925BNP, AR-1927BNF, AR-1928SNF, and AR-1928SNF-2 (DMI Ex. 3).

polyethylene (*i.e.*, including UHMWPE), then it is my opinion that there is infringement under the doctrine of equivalents because any differences are insubstantial.

53. I have used the “function/way/result” test to determine infringement of claims 1, 2, 8, 9, and 12 under the doctrine of equivalents. In particular, I have determined the function/way/result of the claim element that Arthrex contends is not literally satisfied and compared that to the function/way/result of UHMWPE in FiberWire™ and TigerWire™.

54. In my opinion, the “function” of the first fiber-forming material is the same as the function of UHMWPE in Arthrex’s FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	Function of Limitation Under the Doctrine of Equivalents	Function of UHMWPE in FiberWire™ and TigerWire™ Suture Products
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The function of the first set of yarns is to contribute a property that is different than a yarn from the second set.	UHMWPE contributes different lubricity and strength properties to the heterogeneous braid than PET.

55. My opinion regarding the “function” of the first fiber-forming material is supported by the ‘446 Patent. The ‘446 Patent explains that the first fiber forming material is “dissimilar” to the second fiber and the braid of dissimilar yarns provides “outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns” (Tab D at 2:50-52; 3:43-48). Further, the ‘446 Patent explains that it is possible to “tailor the physical” properties by “varying the type and proportion of each of the dissimilar fiber forming materials used” (Tab D at 2:58-61). Further, the patent notes that the different fiber components make different relative contributions to one or more properties of the heterogeneous braid (Tab D at 8:19-21).

56. It is my opinion that the UHMWPE in Arthrex's FiberWire™ and TigerWire™ products has the function as the claimed first fiber-forming material based on an examination of FiberWire™ and TigerWire™ and its manufacturing. In my opinion, the UHMWPE contributes a property or properties that is/are different from the property or properties contributed by the PET. For example, Mr. Hallet testified that, in the development of FiberWire™, he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid. Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of UHMWPE and the flexibility of PET (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 325).

57. In my opinion, the “way” of the first fiber-forming material is the same as the “way” of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	“Way” of Limitation Under the Doctrine of Equivalents	Way UHMWPE performs its Function in FiberWire™ and TigerWire™
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The “way” is at least one yarn from the first set of yarns is in direct intertwining contact with at least one yarn from the second set.	At least one UHMWPE yarn is braided with at least one PET yarn in direct intertwining contact (Dreyfuss 9/16/05 Dep. at p. 99-107).

58. My opinion regarding the “way” of the “first fiber-forming” element is supported by the ‘446 Patent. The ‘446 Patent explains that the way that the first-fiber forming material performs its function is by braiding it with a second dissimilar yarn in direct intertwining contact. For example, the ‘446 Patent states in the “Summary of the Invention” section that the “the invention is a heterogeneous braid comprising a first and second set of discrete yarns in a sterilized, braided construction” and that the at least one yarn from the first set is in “direct

intertwining contact” with a yarn from the second set (Tab D at 2:40-44; *see also* 3:21-28; 3:40-45). The ‘446 Patent further explains that the heterogeneous braid properties are due to the “mechanical interlocking or weaving of the individual yarns” (Tab D at 2:56-58; 3:43-48). Also, during the prosecution history, the applicants explained that the beneficial properties are due to the braiding of direct “intertwining” contact of dissimilar yarns (December 2, 1992 Office Action at 2, emphasis original).

59. Further, the ‘446 Patent describes certain preferred embodiments in which the first fiber-forming materials act as lubricating yarns and the second fiber-forming materials provide strength (Tab D at 4:9-59). The ‘446 Patent also describes other specific preferred embodiments that have PTFE braided in direct intertwining contact with PET to obtain the benefits of each yarn (Tab D at 7:1-8:61). These are all preferred embodiments where the at least one first-fiber forming material is braided in direct intertwining contact with at least one different, second fiber-forming material so that each yarn contributes to the heterogeneous braid. Because these are preferred embodiments, they are an example of the broader disclosed concept of braiding the first and second fiber forming materials so that they can individually contribute to the overall properties of the heterogeneous braid. Notably, the invention is described more broadly than just these “preferred embodiments,” and, therefore, it is my opinion that neither the function, way, or result is limited to the specific properties of the first-forming material in any of the preferred embodiments.

60. It is my opinion that the UHMWPE in Arthrex’s FiberWire™ and TigerWire™ suture products have the same “way” as the claimed first-fiber forming materials. My opinion is based on a visual inspection and observation of FiberWire™ and its manufacturing processes. In my opinion, at least one UHMWPE yarn in Arthrex’s FiberWire™ and TigerWire™ products is

braided in direct intertwining contact with at least one PET yarn. My opinion is supported by Arthrex's and Pearsalls' testimony and documents. For example, Mr. Dreyfuss testified that the adjacent yarns in the FiberWire™ and TigerWire™ sheath are in direct intertwining contact with each other (Dreyfuss 9/16/05 Dep. at p. 99-107).

61. In my opinion, the “result” of the first forming material is the same as the result of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	“Result” of Limitation Under the Doctrine of Equivalents	Result of UHMWPE in FiberWire™
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The result of the first set of yarns is to contribute to the heterogeneous suture braid a property different from the yarn in the second set, so that when they are braided the yarns contribute to the properties of the overall heterogeneous braid.	The result of the PE yarns is to provide a different property than the PET, so that when they are braided the PE yarns contribute properties to the overall heterogeneous braid.

62. My opinion regarding the “result” of the first-forming material is supported by the ‘446 Patent. For example, the ‘446 Patent explains that the “heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials” (Tab D at 2:49-52). Further, the ‘446 Patent states that the “types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.” (Tab D at 1:51-56).

63. My opinion is that FiberWire™ and TigerWire™ suture products have the same claimed result. UHMWPE has and contributes properties that are different from those provided by PET. For example, Arthrex has admitted that the UHMWPE is added to FiberWire™ to increase strength. (Arthrex supplemental response to Interrogatory No. 3) In FiberWire™, when

the UHMWPE is braided with PET, it is my opinion that the UHMWPE contributes to the strength of the overall heterogeneous braid. Further, UHMWPE is known to have relatively high lubricity and has different lubricity than PET.

64. My opinion is further supported by the testimony and documents from Arthrex and Pearsalls witnesses:

Q What did you understand Mr. Grafton to mean when he said:

"Can you build a 25% Dyneema/75% polyester blend in Size 2 that is very flexible".

What did you understand that to mean?

A Yes, that he wanted a braid which was more -- not so stiff.

Q As the 100% ultra high molecular weight polyethylene?

A Yes. (Hallet 1/12/06 Dep. at p. 306:20-307:4, DMI Ex. 324)

Q. Mr. Grafton wanted Pearsalls to braid polyester with the ultra high molecular weight polyethylene so that the polyester could provide flexibility?

A Yes. (Hallet Dep. at p. 307:10-14, DMI Ex. 324)

65. It is my expert opinion that both of the above documents and testimony demonstrate that Arthrex is "tailor[ing] the physical" properties of the braid by "varying the type and proportion of each of the dissimilar fiber forming materials used" as taught by the '446 Patent (Tab D at 2:58-61).

66. In summary, if it is determined that PE is not PE (does not include UHMWPE), it is my opinion that the ultra high molecular weight polyethylene in Arthrex's FiberWire™ and TigerWire™ suture products is equivalent to the claimed PE because it performs the same function, in the same way to achieve the same result. Any differences are insubstantial in the context of the invention.

VI. Opinions Regarding Contributory Infringement

67. I understand that contributory infringement is defined in 35 U.S.C. §271(c), which provides:

Whoever offers to sell or sells within the United States or imports into the United States a component of a Patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a Patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such Patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

68. I understand that an act of actual direct infringement is necessary for a finding of contributory infringement. If there is direct infringement, then there is contributory infringement if the remaining requirements of the statute are satisfied.

69. I have been asked to provide my opinion as to whether Pearsalls has sold within the United States or imported into the United States a component of a patented suture that constitutes a material part of the invention in claims 1, 2, 8, 9 and 12 of the '446 patent. It is my opinion that Pearsalls has sold within the United States or imported into the United States a component of a patented suture constituting a material part of the invention in claims 1, 2, 8, 9 and 12 of the '446 patent.

70. It is my understanding that Pearsalls makes all of the braids used in Arthrex's FiberWire™ and TigerWire™ suture products. (Arthrex's Response to Mitek Interrogatory #2). Pearsalls imports into the United States unsterile, FiberWire™ and TigerWire™ suture that has not been cut to length or tipped. I personally observed the Pearsalls braided product at the final inspection stage before shipment. Pearsalls also sells within the United States this unsterile, FiberWire™ and TigerWire™ suture to R.K. Manufacturing (Ponton Dep. at p. 17:23-18:12).

71. It is my opinion that the unsterile FiberWire™ and TigerWire™ that Pearsalls imports and sells is a component of the invention of claims 1, 2, 8, 9 and 12 of the '446 Patent. The imported and sold FiberWire™ and TigerWire™ has the same construction as that sold by Arthrex except for some processing operations such as tipping, attachment to anchors or needles, and sterilization. (Ponton Dep. at p. 18:18-21). Thus, the imported and sold FiberWire™ and TigerWire™ has all of the limitations of claims 1, 2, 8, 9, and 12 except that it is not sterilized. It has a braid construction of polyethylene and PET in direct intertwining contact. Further, each has a core except for size 4-0 FiberWire™. Thus, the FiberWire™ and TigerWire™ that is sold and imported by Pearsalls is a component of the claims of 1, 2, 8, 9, and 12 and a material part of the invention of claims 1, 2, 8, 9, and 12.

72. I have been asked to provide my opinion as to whether the FiberWire™ and TigerWire™ imported and sold by Pearsalls is especially adapted for use for infringement of claims 1, 2, 8, 9, and 12 of the '446 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use. It is my opinion that the FiberWire™ and TigerWire™ imported and sold by Pearsalls is especially adapted for use in an infringement of the '446 Patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use. The '446 Patent claims a suture. It is my understanding that RK Manufacturing does nothing to alter the FiberWire™ and TigerWire™ surgical braid. (Ponton Dep. at p. 18:18-21). The FiberWire™ and TigerWire™ imported and sold by Pearsalls has no known use other than as a suture, which is claimed in the '446 Patent. Thus, the FiberWire™ and TigerWire™ that is imported and sold by Arthrex is not a staple article of commerce and has no known substantial noninfringing use other than that that has been identified. (Pearsalls' Answers to Mitek's First Set of Interrogatories).

VII. Other Issues

73. It is my opinion that some of the benefits of FiberWire™ and TigerWire™ that are marketed by Arthrex are due to the patented invention, a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the heterogeneous non-bioabsorbable braid.

74. For example, Arthrex markets that FiberWire™ has superior strength, increased stiffness, and has been “enthusiastically endorse[d]” for “its feel.” (DMI Ex. 7 at 2). FiberWire™’s and TigerWire™’s ultra high molecular weight polyethylene braided yarns contribute to FiberWire™ and TigerWire™’s strength and stiffness (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 267). Further, FiberWire™’s and TigerWire™’s PET contributes to the flexibility of the braid (DMI Ex. 324). Notably, the patented invention of claims 1, 2, 8, 9, and 12 includes a heterogeneous braid of PE and PET. Further, the ‘446 patent explains that a heterogeneous braid of dissimilar materials in direct intertwining contact can contribute to the overall properties of the heterogeneous braid (Tab D at 2:50-52; 3:43-48). Further, the ‘446 patent teaches that the braided yarns can be tailored in type and amounts to obtain the properties of each (Tab D at 2:58-61). FiberWire™ and TigerWire™ do just that by braiding polyethylene and PET. Thus, it is my opinion that benefits touted by Arthrex are due to the patented invention.

75. Arthrex’s and Pearsalls’ development of FiberWire™ and TigerWire™ confirms my opinion. For example, Mr. Hallet testified that in the development of FiberWire™ he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid. Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of

UHMWPE and the flexibility of PET (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 325).

76. It is my opinion that the braiding of dissimilar materials in direct intertwining contact in FiberWire™ contributes to the properties advertised by Arthrex in its marketing literature. For example, Arthrex has marketed that “that FiberWire™ is a “Braided Polyblend Suture” that it is “revolutionizing Orthopaedic Surgery” (DMI Ex. 7 at 1). I also note that Arthrex’s claims that its FiberWire™ heterogeneous braid has superior properties is supported by “multiple scientific publications” (DMI Ex. 7 at 2). Thus, Arthrex is highlighting the braiding of dissimilar materials as claimed in claims 1, 2, 8, 9, and 12 of the ‘446 Patent.

77. Further, Arthrex has made many assertions that FiberWire™’s heterogeneous braid is superior to Ethibond’s homogeneous braid. For example, Arthrex claims that the FiberWire™ is “twice as strong” as “polyester suture” (DMI Ex. 9 at 2; DMI Ex. 10 at 2; *see also* DMI Ex. 11; DMI Ex. 24 at ARM001473). Arthrex also asserts that “FiberWire™ has twice the strength of the similar *sized generic suture* with superior feel, tie ability, and lower knot profile” (DMI Ex. 13; *emphasis added*). Arthrex claims that its studies show that FiberWire™ has better knot strength than “Ethibond Excel braided polyester suture” (ARM002177-8; ARM002181-83; ARM002188-2191). It is my opinion that the braiding of polyethylene and PET in direct intertwining contact contributes to FiberWire™’s properties of strength and flexibility that Arthrex markets with respect to Ethibond.

78. At trial, I may use demonstrative exhibits. For example, I may use demonstrative exhibits to explain the design and construction of Arthrex’s FiberWire™ and TigerWire™ suture products, to explain infringement, and to explain the other opinions that I have set forth in my report.

Dated: March 3, 2006

A handwritten signature in black ink, consisting of a series of loops and a long horizontal stroke extending to the right.

David Brookstein, Sc.D.
Fellow-American Society of Mechanical Engineers

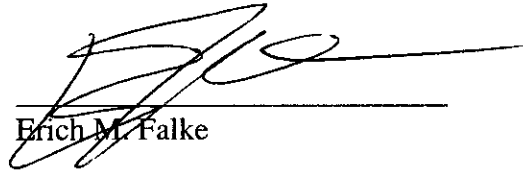
CERTIFICATE OF SERVICE

I certify that the foregoing Expert Report of Dr. David Brookstein was served by e-mail without exhibits and Federal Express overnight mail (Saturday delivery) with exhibits on March 3, 2006 on the following:

Charles W. Saber
Dickstein, Shapiro, Morin & Oshinsky, LLP
2101 L. Street, NW
Washington, DC 20037-1526.

Christopher Weld, Jr.
Todd & Weld LLP
28 State Street, 31st Floor
Boston, MA 02109

Dated: March 3, 2006



Erich M. Falke

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.,)	
a Private Limited Company)	
of the United Kingdom,)	
)	
Defendants.)	

Expert Report of Dr. Matthew Hermes

I. Background Information

A. Professional Experience

1. From 1983-95, I was employed with U. S. Surgical Corp. In 1983, I started as Senior Research Scientist. My duties from 1983-1986 included developing products based on bio-absorbable materials for use as medical devices. From 1986-1992, I initiated and led the first suture development program at U.S. Surgical. That program led to the commercialization of the Syneture™ suture product line. My responsibilities included all phases of surgical suture development from concept to commercialization. My suture group included seventeen team members directly involved in the design and development of commercial surgical suture products, including suture design and manufacture, fiber extrusion and processing, fiber design, yarn design, braiding specifications, selection of materials, braid design, prototype braiding, braid post

treatment, stretching, annealing, coating, packaging design, sterilization, testing, assisting with obtaining 510(k) approval, and quality control.

2. In 1996, I authored the book "Enough for One Lifetime," the biography of Wallace Carothers, the inventor of Nylon. While writing this book from 1989-1996, I researched and studied the origins of synthetic fiber science including the history and development of nylon and polyester.

3. Before I worked at U.S. Surgical Corporation, I was a Research Director at Virginia Chemicals, at Celanese Co. from 1979-1983. Prior to being a Research Director, I was a Research Chemist, Supervisor, at E. I. DuPont from 1959-1979. At DuPont, I work with triaxial support systems and supervised a group that worked on elastomer coated fabrics.

4. From 1992-1994, I was an Adjunct Professor of Chemistry at the University of Wyoming. From 1995-1997, I was a Consultant at Colorado Advanced Technology Institute. In 2001 and 2006, I received two Small Business grants from the NIH for the development of unique all plastic manual wheelchairs and worked with Turbo Wheelchair company to develop, manufacture, and sell these unique devices.

B. Education

5. I have a Bachelor of Science in Chemistry from St. John's University, Brooklyn, NY, 1955. I have a Ph. D. in Chemistry from the University of Maryland, 1959. My mentor was Professor William Bailey who developed one of the earliest polymer science research groups in the country. My doctoral thesis related to polymers made using the Diels-Alder reaction. I also have a Masters of Arts in Liberal Studies from Wesleyan University, 1992.

6. A copy of my CV is attached under Ex. 1. A list of my publications and patents are set forth in my CV. In the past four years, I have not been deposed or testified as an expert witness.

7. I am being compensated at my customary hourly rate of \$200/hr. My compensation is not based on the outcome of the litigation.

II. Summary of Opinions

8. It is my opinion that claims 1, 2, 8, 9, and 12 of U.S. Patent No. 5,314,446 Patent ("the 446 Patent") (Ex. 2) are not invalid for obviousness over U.S. Patent No. 4,610,688 ("the 688 patent") when combined with U.S. Patent No. 5,120,802 ("the 802 patent"), the Dyneema SK60, High strength/high modulus fiber, Properties & Applications ("the DSM brochure")¹; and/or the general teachings of the art as defined by Dr. Mukherjee.²

9. It is my opinion that claims 1, 2, 8, 9, and 12 of the 446 Patent are not anticipated by U.S. Patent No. 5,318,575³ ("the 575 patent") because the 575 patent does not teach, either expressly or inherently, all of the claimed limitations of these claims.

10. If the claims of the 446 Patent are construed to mean that "PE" includes UHMW PE, it is my opinion that claims 1, 2, 8, 9, and 12 of the 446 Patent are not invalid for obviousness over U.K. patent application No. 2,218,312A to Burgess ("Burgess") and i) Cohan, et al., An Evolution of Ultrastrong Polyethylene Fiber as an Ophthalmic Suture, Arch Ophthalmol – Vol. 103, December 1985 ("Cohan"); ii) the DSM brochure; and/or iii)

¹ I understand that there are legal requirements for whether a document qualifies as prior art. I also understand that the DSM Brochure may not be prior art. For purposes of this report, I have been asked to assume that it qualifies as prior art.

² Dr. Mukherjee does not opine on the validity of claims 3-7 and 10-11 of the 446 over the references that he cites. I was not asked to consider the validity of claims 3-7 and 10-11 of the 446 patent over the references cited by Dr. Mukherjee.

³ I understand that there are legal requirements for whether a document qualifies as prior art. I also understand that Chesterfield may not be prior art. For purposes of this report, I have been asked to assume that Chesterfield qualifies as prior art.

either one of U.S. Patent No. 4,563,392 or U.S. Patent No. 4,543,286 (“Harpell patents”).

11. If the claims of the 446 Patent are construed to mean that “PE” includes UHMW PE, it is my opinion that the claims of the 446 patent are not invalid for failing to satisfy the written description requirement because the 446 Patent specification describes the claimed invention sufficiently to convey to a person of skill in the art, that the inventors had possession of the sutures recited in the 446 patent claims, at the time the patent application for the 446 patent (February 1992) was filed with the U.S. Patent & Trademark Office.

12. If the claims of the 446 Patent are construed to mean that “PE” includes UHMW PE, it is my opinion that the claims of the 446 Patent are not invalid for failing to satisfy the enablement requirement because the claimed invention is sufficiently disclosed, such that a person of skill in the art, at the time the patent application for the 446 patent was filed with the U.S. Patent & Trademark Office (February 1992), could make and use the sutures claimed in the 446 Patent, without undue experimentation based on the 446 patent’s description of the claimed sutures.

13. It is my opinion that the inventors actually reduced to practice the inventions recited in claims 1, 8, and 9 of the 446 Patent at least as early as February 1989 and certainly at least as early as December 1989.

14. It is my opinion that, Mr. Goodwin’s and Dr. Steckel’s statements, that Mr. Witherspoon said were materially inconsistent were not inconsistent, much less materially inconsistent.

15. I may testify about certain suture properties and suture testing.

III. Legal Framework for My Opinions

16. The patent laws form the legal framework for my opinions. My understanding of the U.S. Patent Laws is as follows. I understand that the patent statute states that patents are presumed valid. 35 U.S.C. §282. I further understand that each patent claim is presumed valid, and therefore an invalidity analysis must be done on a claim-by-claim basis. I understand that because of this presumption, Arthrex or Pearsalls must put forth “clear and convincing” evidence of invalidity to overcome this presumption of validity. It is my understanding that this a higher burden of proof than a preponderance of the evidence standard, but less than a reasonable doubt standard.

A. The Law of Anticipation

17. It is my understanding that a patent claim is invalid if it is not novel (which I understand is referred to as being “anticipated”), if a single prior art reference teaches, expressly or inherently (necessarily present), all of the claim limitations arranged in the same manner as the claim and enables one of ordinary skill in the art to make and use the invention. I understand that the test for lack of novelty is generally a two-part test. First, the meaning and scope of the claims are determined by the Court. Second, once the claim scope has been determined or construed, the next step in assessing a patent claim’s validity is deciding whether one piece of prior art describes all of the claim limitations arranged as claimed. Because the Court has not yet construed the claims of U.S. Patent No. 5,134,446, I have been asked to assume a certain claim construction.

B. The Law of Obviousness

18. I also understand that a claim is invalid due to obviousness under 35 U.S.C. §103 if there is clear and convincing evidence showing that the differences between the claim and the prior art are such that the claimed subject matter as a whole would have

been obvious to a person having ordinary skill in the art at the time the invention was made.

19. I understand that determining obviousness involves the following four factual inquiries: 1) the scope and content of the relevant prior art; 2) the level of ordinary skill in the art; 3) the differences between the claimed invention and the prior art; and 4) secondary considerations of non-obviousness.

20. I understand that the “scope and content of the relevant prior art” includes all art that is reasonably pertinent to the particular problem with which the invention was involved. In other words, the relevant art is defined by the nature of the problem confronting the would-be inventor. The relevant prior art encompasses art in the inventor’s field of endeavor and any analogous art.

21. I understand that “analogous prior art” is art that, although not within the inventor’s field of endeavor, is still reasonably pertinent to the particular problem to be solved. I understand that a reference is “reasonably pertinent” if, even though it may be in a different field from that of the inventor’s endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering the problem.

22. In the case where obviousness is based on the combination of prior art references, I understand that there must be a reason, suggestion, or motivation in the prior art or elsewhere, that would have led a person of ordinary skill in the art to combine the prior art references to arrive at the claimed invention. The relevant inquiry is whether a skilled artisan, confronted with the same problems as the inventor, and with no knowledge of the claimed invention, would select the elements from the prior art for

combination in the manner claimed. In selecting prior art references relevant to the obviousness inquiry, it is considered improper “hindsight” to define the problem to be solved in terms of its solution (*i.e.*, the claimed invention).

23. I also understand that it is not enough to find every element of a claimed invention in the prior art. There must be a reason, suggestion, or motivation to combine the prior art in such a way so as to arrive at the claimed invention.

24. I understand that so-called “secondary considerations of non-obviousness,” when present, must also be considered as part of the obviousness determination. I understand that these are objective evidence of non-obviousness, and include, among other things, evidence of commercial success, copying, long-felt but unresolved need, failure of others, unexpected results created by the claimed invention, unexpected properties of the claimed invention, licenses showing industry respect for the invention, skepticism of persons skilled in the art before the invention, and tribute by others. These secondary considerations provide objective evidence of how the patented device is viewed in the marketplace by those directly interested in the product.

C. The Law of Written Description & Enablement

25. I understand that another condition of validity is that a patent must describe the invention sufficiently to convey to a person of skill in the art that the patentee had possession of the claimed invention at the time of the application, *i.e.*, that the patentee invented what is claimed.

26. I understand that another condition of validity is that a patent must describe the manner and process of making and using the invention so as to enable a person of skill in the art to make and use the invention without undue experimentation. I understand that routine details do not need to be disclosed in a patent because they are readily

apparent to one of ordinary skill in the art and that patent specifications need not be as detailed as production specifications.

D. Actual Reduction to Practice

27. I understand that invention requires a conception and reduction to practice. I understand that conception is the formulation of an idea in one's mind of a definite and permanent idea. I further understand that actual reduction to practice typically occurs when the claimed invention is constructed and evaluated sufficiently to know that it will work for its intended purpose.

IV. Claim Construction

28. As mentioned above, I understand that the first step in an invalidity analysis is to determine the meaning of the claims. I understand that the Court will determine the meaning of the claim terms in the 446 Patent. Until the Court determines the meaning of the claims, I have been asked to assume the meaning of the following claim terms.

“PE” – means all types of polyethylene (PE) including ultra high molecular weight polyethylene.

“Consisting essentially of” – means the claimed suture with all of its limitations and any other unlisted materials that do not materially affect the basic and novel characteristics of the claimed suture.

I have been told that the Court will determine the basic and novel characteristics of the claimed invention. I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid.

“Direct intertwining contact” means the mechanical interlocking or weaving of the individual yarns that make up the suture braid.

“Volume fraction of the first set of yarns in the braided sheath and core” means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture.

I reserve the right to modify my opinion should the Court determine the meaning of the claims are different than the above constructions.

V. Materials Considered in Forming My Opinions

29. In forming my opinions, I have considered the 446 Patent, its file history, and the reports of Dr. Debi Prasad Mukherjee and John F. Witherspoon, and Peter Dreyfuss’s, Brian Hallet’s, and Dr. Mark Steckel’s, and Mr. Donald Grafton’s deposition testimony.

A list of the documents that I used in forming my opinions is set forth in Ex. 16.

VI. Claims 1, 2, 8, 9, & 12 of the 446 Patent Are Not Invalid Over the References Discussed by Dr. Mukherjee

A. The Level Of Ordinary Skill In The Art

30. I understand that Dr. Mukherjee has opined that a person of ordinary skill in the art, “in February 1992, had an undergraduate degree in engineering or science and several years (e.g., approximately 3-5) experience with manufacturing and/or processing of fibers and sutures which can be used for biomedical applications.”

(Mukherjee at 10). I disagree because this definition of ordinary skill is too broad. It encompasses persons who do not have any relevant technical degrees and relevant experience. For example, Dr. Mukherjee’s definition includes someone with no education that is relevant to suture design and no suture design experience.

31. In my opinion, between 1988-1992, a person of *ordinary* skill in the art would likely be a scientist in chemistry or a chemical, mechanical, or biomedical, biomechanical, or textile engineer (or other similar technical field) practicing in the field of suture design or development and having about 2 to 3 years of experience in the suture design field or person without such a degree but having about eight years experience in suture design or development. In my opinion, between 1988-1992, a person of skill in the art would likely be a scientist in chemistry or a chemical, mechanical, or biomedical, biomechanical, or textile engineer (or other similar technical field) practicing in the field of suture design or development and having about 1 to 2 years of experience in the suture design field or person without such a degree but having about five years experience in suture design or development.

32. Both the person of ordinary skill in the art and the person of skill in the art would have known that a broad spectrum of sutures were available for surgical use between 1988-1992. During that period of time, commercial sutures generally were classified as either monofilaments or multifilaments.

33. Both the person of ordinary skill in the art and the person of skill in the art would also have known that sutures are designed based on a balance of several properties including, among others, knot strength, knot security, pliability, tissue drag, run down, absorbability, and biocompatibility. Also, one of ordinary skill in the art would have understood that generally monofilaments and multifilaments possessed different properties giving them advantages and disadvantages over each other. For example, generally, monofilaments had less tissue drag, but would lack relative pliability and knot security, when compared to multifilaments. Whereas, multifilaments, generally, would

be more pliable and have greater knot security, but relative poor knot run down and tissue drag, when compared to monofilaments.

B. Claim 1 of the 446 Patent Is Not Invalid For Obviousness Over The 688 Patent When Combined With The 802 Patent, the DSM Brochure, And/Or The General Teachings Of The Art As Defined By Dr. Mukherjee

34. I understand that Dr. Mukherjee has opined that claims 1, 2, 8, and 12 of the 446 Patent are invalid as obvious over the 688 patent when combined with the 802 patent, the DSM Brochure and/or the general teachings of the art as defined by Dr. Mukherjee (Mukherjee at 3, 13). I disagree with Dr. Mukherjee's opinions for the reasons set forth below.

1. The Scope And Content Of The 688 Patent, The 802 Patent, & The DSM Brochure

35. Below I discuss the scope and content of the 688 patent, the 802 patent, and the DSM brochure as they would have been understood by a person of ordinary skill in the art between 1988 and 1992.

a) The Scope & Content of the 688 Patent

36. The 688 patent teaches a ligament prosthesis, not a suture (Ex. 3 at 2:14). Dr. Mukherjee agrees (Mukherjee at 11). According to the 688 patent, the disclosed ligament prosthesis is designed to have a "yield strength in tension and a longitudinal elasticity that are at least as comparable to that of a human ligament and a resistance of longitudinal elastic deformation in tension that approximates that of a human ligament" (Ex. 3 at 2:16-19). The 688 patent teaches a tubular triaxial-fabric braided element (Ex. 3 at 3:49-50) having three sets of fibers, designated 9, 11, and 13 (Ex. 3 at 3:65-66). Fibers 9 are straight, and fibers 11 and 13 are helically disposed in the wall of the tubular fabric prosthesis (Ex. 3 at 3:66-4:3). The 688 patent teaches that the straight

fibers 9 are made from a group of materials one of which is hard elastic polypropylene (Ex. 3 at 5:50-57). Fibers 11 and 13 are made from a different group of materials, but are taught to be the same in a given prosthesis (Ex. 3 at 5:57-6:2; Table of Fibers). The triaxial braid taught by the 688 patent is manufactured on a triaxial braiding machine (Ex. 3 at 4:14-36).

b) The Scope & Content of the 802 Patent

37. The 802 patent describes that the potential biological or medical uses of block copolymers having carbonates as their major component had not been appreciated (Ex. 4 at 1:35-36). Accordingly, the 802 patent teaches a polycarbonate-based, block copolymer having at least one flexible block and at least one block, which is more crystalline than the first flexible block (Ex. 4 at 1:6-9). The 802 patent provides examples of the two blocks, which it refers to as “A” and “B” blocks (Ex. 4 at 2:47-3:60). It provides a more detailed description of specific block copolymers throughout the patent (Ex. 4 at 4:8-44; 4:48-12:30). The main focus of the 802 patent to one of ordinary skill in the art between 1988 and 1992 is specific block-copolymer structures that may have useful applications.

38. According to the 802 patent, the block copolymers that it teaches are “particularly suited to be spun into fibers, extruded into films, tubings, and devices of many shapes and sizes” (Ex. 4 at 1:9-12; see also 12:55-65). The 802 patent describes many general applications for the block polymer including forming fibers or yarns that may be “woven, braided and/or knitted into fabrics having various structural configurations” (Ex. 4 at 15:41-42). Also, the 802 patent states that the block copolymers can be formed into fibers that are “preferably used as sutures or fasteners” (Ex. 4 at 15:44-45). The 802 patents states that the block copolymers that are “particularly useful are woven or

knitted fabrics in the form of tubular prostheses of varying shapes, lengths, and diameters” and illustrative of these tubular prosthesis are “vascular grafts, nerve guidance channels, and the like” (Ex. 4 at 15:60-62).

c) The Scope & Content of the DSM Brochure

39. DSM is a company that manufactures fibers for use in different applications. The DSM brochure advertises that Dyneema SK60 can be used for many different applications, including, cable, bow strings, ropes, strings, sutures, ligaments and long line and sport sea fishing (Ex. 5 at PR08424). The DSM brochure describes that polyethylene properties cover the range from 1 N/tex specific strength and 25 N/tex specific modulus to 3.5 N/tex specific strength and 150 N/tex specific modulus (Ex. 5 at PR08422). It also notes that Dyneema SK60 falls within this range at 2.7 N/tex and 90 N/tex (Ex. 5 at PR08422). Accordingly to the brochure, the Dyneema SK60 was a new material, and it further notes the knot strength of certain SK60 fibers, not braids (Ex. 5 at PR08426). The brochure does not mention knot security, provide any analysis regarding the knot security of Dyneema SK60N, or provide any specific analysis of properties associated with braids (Ex. 5).

40. There is no discussion in the Dyneema brochure of a heterogeneous braid. There is no discussion in the DSM Brochure of using PET, Nylon, or aramid in combination with UHMW PE fibers. Further, there is no description of how to construct braids or using Dyneema fibers to make braided sutures.

41. I note that the DSM brochure provided with Dr. Mukherjee’s report (Ex. 7 of Mukherjee report) is not completely readable. For example, the knot strengths of the fibers are not readable. Thus, I am not able to comment on the teachings of the DSM

brochure as a whole. I understand, however, that a reference is supposed to be considered as a whole based on all of its teachings.

2. The Differences Between The 688 Patent, the 802 Patent, the DSM Brochure, And Claim 1 of the 446 Patent

42. Claim 1 of the 446 Patent claims a *suture* (Ex. 2 at 8:62-10:19). The 688 patent does not teach a suture.

43. Claim 1 of the 446 Patent claims certain yarns that are braided in “direct intertwining contact” (Ex. 2 at 8:67). The 688 patent also lacks a yarn from the claimed first set of fiber-forming materials yarns braided in “direct intertwining contact” with a yarn from the claimed second set of fiber-forming materials.

44. Dr. Mukherjee has opined that (i) the first-fiber forming material of claim 1 of the 446 Patent is fiber set 9 in the 688 patent; (ii) the claimed second-fiber forming material of claim 1 of the 446 patent is either fiber set 11 or 13 in the 688 patent; and (iii) the claimed direct intertwining contact of claim 1 of the 446 patent is the braiding of fiber set 9 with either fiber set 11 or 13 in the 688 patent (Mukherjee at 11-12). I disagree. Element 9 in the 688 patent is a straight fiber, while the elements 11 and 13 are helically wound around element 9 (Ex. 3 at Fig. 1 & 2; 3:65-4:14). Thus, element 9 is not mechanically interlocked with either element 11 or 13 and is not braided with either element 11 nor 13 “in direct intertwining contact,” as claimed in the 446 Patent. For example, in a direct intertwining braided construction, one set of yarns is interlocked with the other, so that they are held within the braid by the other set of yarns (see Ex. 2 at 5:18-26). In contrast, in the 688 patent, fibers 9 are not interlocked with fibers 11 or 13.

45. There are also differences between claim 1 of the 446 patent and the 802 patent. Claim 1 of the 446 Patent recites a *heterogeneous braid* of two yarns, a *direct intertwining contact* braid of braided yarns, and *specific yarns* in the braid (Ex. 2 at 8:63-9:10). Although the 802 patent discloses a suture of certain copolymers, the 802 patent does *not* recite a heterogeneous braid of two yarns, a direct intertwining contact braid of yarns, nor the specific yarns claimed in the 446 patent in a braid. Rather, the 802 focuses on a new block copolymer structure and mentions general applications for it. There is no mention of braiding the claimed materials as braided in claim 1 of the 446 patent. Thus, although the 802 patent refers to a suture, it is missing most of the other claim elements.

46. Similarly, there are also differences between the invention of claim 1 of the 446 Patent and the DSM Brochure. Claim 1 of the 446 patent claims a heterogeneous braid (Ex. 2 at 8:63-9:10). The DSM brochure does not disclose or suggest a heterogeneous braid.

47. The 446 Patent claims a heterogeneous braid of PE with nylon, aramid, or PET (Ex. 2 at 8:63-10:19). The DSM brochure does not disclose or suggest using nylon, aramid, or PET with Dyneema at all, let alone in a suture, or in a heterogeneous braided suture wherein dissimilar yarns are in direct intertwining contact.

3. One of Ordinary Skill in the Art Would Not Have Been Motivated To Combine The 688 Patent And The 802 Patent At The Time Of The Invention To Form The Suture Of Claim 1 Of The 446 Patent

48. Dr. Mukherjee opines that one of skill in the art would have been motivated to combine the 688 and 802 patents in such a way so as to form the claimed invention (Mukherjee at 13). I disagree because there are significant differences between the 688

and 802 patents and the invention of claim 1 of the 446 patent. Further, there is no suggestion or teaching to modify them or combine them in such a way, so as to form the suture of claim 1 of the 446 patent.

49. There is no motivation to modify either the 802 or 688 patents in light of the teachings of the other to form the claimed invention.

50. One of ordinary skill in the art would not have not have been motivated to modify the 688 patent in light of the 802 patent to form the claimed invention because there are significant differences between the suture of claim 1 of the 446 patent and the 688 and 802 patents. Neither the 688 patent nor the 802 patent teaches a suture having a heterogeneous braid in direct intertwining contact. Further, neither teaches the materials claimed in the 446 patent braided in direct intertwining contact. Given these significant differences, one of ordinary skill in the art would not have been motivated to form the claimed invention from the 688 and 802 patents.

51. Dr. Mukherjee has opined that merely because the 802 patent discloses a block copolymer that can be used as a suture or in a ligament prosthesis, one of ordinary skill in the art would have been motivated to modify the tubular prosthesis of the 688 patent into the invention of claim 1 of the 446 patent. But the triaxial-braided fabric element of the 688 patent is braided on a triaxial braider. One of ordinary skill in the art at the time of the invention would not have been motivated to form a suture, as recited in claim 1 of the 446 Patent, based on the teachings of the 688 patent, because the claimed suture could not be made with a triaxial braider. Notably, a triaxial braider is generally used for larger woven tubular structures, not sutures. For example, the 688 patent examples 1 and 2 are hollow-tubular prostheses that have a circumference of about 21 and 19 mm

(Ex. 3 at 8:58-9:17). In contrast, sutures generally have a diameter on the order of less than 2 mm in diameter (See Ex. 11 at sec. 24) (a #2 suture is about 0.55 mm. in diameter). The structure taught by the 688 patent is simply too big for use as a suture.

52. I also disagree with Dr. Mukherjee's suggestion that the ligament prosthesis taught by the 688 patent could just be used as a suture. The structure taught by the 688 patent would have to be significantly modified to be a suture. Dr. Mukherjee provides no explanation of how one of ordinary skill in the art would have been motivated to change the triaxial-braided fabric disclosed in the 688 patent into a suture. Also, he provides no explanation of how the teachings of the 688 patent can be applied to the braiding equipment that is used for sutures to form a braid as claimed. Nor does the 802 patent provide any such explanation.

53. I further disagree with Dr. Mukherjee's opinion that just because the 802 patent references sutures and prosthesis, it provides motivation to change the ligament prosthesis of the 688 patent in such a way so as to form the suture of claim 1 of the 446 patent. The 688 patent teaches a ligament prosthesis that should be designed to have elastic behavior that matches the physical properties of the ligament being repaired (Ex. 3 at Fig. 5; 7:29-33). One of ordinary skill in the art at the time of the invention would have known that sutures generally are designed not to have elastic behavior that matches a ligament's physical properties. Sutures have a different function than the ligament disclosed in the 688 patent. Generally, sutures hold tissue together during the healing process. Therefore, sutures are typically designed to have some elasticity, but less elasticity than the ligament prosthesis taught by the 688 patent. Thus, between 1998-1992, one of ordinary skill in the art reading the 688 and 802 patents would have

recognized the differences between the tubular ligament prosthesis of the 688 patent and a suture, and would not have been motivated to modify the ligament prosthesis of the 688 patent into a suture, let alone into the suture recited in claim 1 of the 446 patent.

54. Dr. Mukherjee appears to say that there is motivation to combine the 688 and 802 patents because “the arts of the braided ligament prosthetics and braided sutures are so similar” (Mukherjee at 11) and because “teachings of the suture field were often applied to teachings of the prosthetics field, and vice versa” (Mukherjee at 12). In this instance, I disagree because the properties of the ligament prosthesis taught by the 688 patent and a suture are much different as described above. Further, the 688 ligament prosthesis is not suitable for use as a suture. Moreover, Dr. Mukherjee has not pointed to any motivation to combine the references in such a way so as to form the claimed invention. The mere fact that the 802 patent refers to both sutures and ligaments does not provide motivation to modify the 688 patent teachings in such a way, so as to form the suture of claim 1 of the 446 patent.

4. One of Ordinary Skill in the Art Would Not Have Been Motivated to Combine the 688 Patent with the DSM Brochure To Form The Suture of Claim 1 of the 446 Patent

55. Dr. Mukherjee has opined that one of ordinary skill in the art would have been motivated to combine the 688 patent and the DSM Brochure in such a way so as to form the claimed invention. I disagree because there are significant differences between the 688 patent and the DSM brochure and the suture of claim 1 of the 446 patent, and there is no suggestion or teaching in them to combine them in such a way so as to form the suture of claim 1 of the 446 patent.

56. There was no explicit motivation in either the 688 patent or the DSM brochure to modify either in light of the teachings of the other to form the claimed invention.

57. As explained above with reference to the combination of the 688 and 802 patents, there are significant differences between the 688 patent and claim 1 of the 446 patent. The 688 patent does not describe a suture. Nor does the 688 patent describe the claimed yarns of the 446 patent in direct intertwining contact. Also, the DSM brochure fails to describe any braiding operations, braiding constructions for a suture, heterogeneous braids, or the material claimed in the 446 patent. Thus, the DSM brochure does not cure the deficiencies in the teachings of the 688 patent. Because of the significant differences and a lack of any explanation in the 688 patent or the DSM brochure as to how to overcome these differences, there is no motivation to combine or modify them in such a way so as to form the suture of claim 1.

58. As described above, the ligament prosthesis taught by the 688 patent would have to be significantly modified in order to be formed into a suture, much less the suture of claim 1 of the 446 patent. The DSM brochure does not describe how to modify the triaxial braided ligament prosthesis of the 688 patent into a suture, much less the suture of claim 1 of the 446 patent. Therefore, for similar reasons as described above with reference to the 802 patent, there is no motivation to modify the ligament prosthesis of the 688 patent into suture.

59. Dr. Mukherjee cites to the DSM brochure for the mere proposition that it "recommends UHMWPE for both suture and ligaments together" (Mukherjee at 13). But this citation say nothing about how to modify the tubular prosthesis taught by the 688 patent to form the suture of claim 1 of the 446 patent. Thus, one of ordinary skill at the

time having the 688 patent and the DSM brochure would not have been motivated to modify the tubular prosthesis taught by the 688 into the suture claimed in the 446 patent.

5. One of Ordinary Skill in the Art Would Not Have Been Motivated to Combine the 688 Patent with the General State of the Art At The Time Of The Invention To Form The Suture of Claim 1 of the 446 Patent

60. Dr. Mukherjee also opines that the 446 Patent claims are obvious over the 688 patent when combined with the “general state of the art” (Mukherjee at 13). He appears to state that the general state of the art is that “teachings of the suture field were often applied to teachings of the prosthetics field, and vice versa” (Mukherjee at 12). But this does not provide motivation to modify the ligament prosthesis taught by the 688 patent to form the claimed suture because it does not describe how to (i) modify the triaxial tubular prosthesis of the 688 patent to form a suture; (ii) how to make a suture having the same structure as the triaxial tubular prosthesis of the 688 patent; or (iii) how to modify the triaxial tubular prosthesis of the 688 patent to have the limitations of the suture of claim 1 of the 446 Patent, including direct intertwining contact between the first and second fiber-forming materials.

6. Secondary Considerations of Non-obviousness

61. I also understand that commercial success of the claimed invention is indicative of the non-obviousness of the suture claimed in the 446 patent. I assume that the FiberWire products are covered by claims 1, 8, 9, and/or 12 of the 446 patent.

62. I have reviewed portions of Dr. Gering's report on damages.⁴ The report shows the large number of sales of FiberWire products, and less sales of TevDek products (Gering Rpt. at 10-11). I understand that Tevdek is a braided polyester suture (Ex. 12 at 36:17-18; 36:25-37:1). Dr. Gering's report also shows that the FiberWire suture drove the sale of Arthrex's suture anchor products because the same Arthrex anchor was sold with FiberWire and Tevdek suture and the FiberWire products outsold the Tevdek products (Gering Rpt. at 7-13).

63. I also note that Mr. Grafton described Arthrex's Tevdek suture as not acceptable (Ex. 12 at 45-46), thereby indicating that the attributes of FiberWire relative to Tevdek have been a reason for the sales of its FiberWire products. For example, Mr. Grafton testified that Arthrex was having "issues from customers with the Tevdek suture being low tensile strength as compared to competitors' suture anchors with suture, primarily Ethicon" (Ex. 12 at 44:13-16). He further explained that surgeons, who were friendly to Arthrex, had broken Tevdek sutures when trying to tie knots (Ex. 12 at 44:18-45:9). According to Mr. Grafton, the solution to this commercial problem was braiding UHMW PE with PET in direct intertwining contact (Ex. 12 at 44:5-54:5). Thus, Mr. Grafton's experience with TevDek and FiberWire confirms that FiberWire has been successful due to its braid construction which is claimed in the 446 patent.

64. I have also reviewed ¶¶ 73-77 of Dr. Brookstein's report. In his report, he describes that FiberWire's benefits that are marketed by Arthrex are due to the features claimed in the 446 patent. Based on Dr. Brookstein's report, Mr. Grafton's testimony, and Dr. Gering's report, FiberWire's commercial success can be attributed to the suture

⁴ I assume that Dr. Gering's and Dr. Brookstein's reports are true. I am not opining on the issues for which they are opining.

claimed in the 446 patent. Thus, FiberWire's commercial success reflects the non-obviousness of at least claims 1, 2, 8, 9, and 12 of the sutures claimed in the 446 patent.

65. I also understand that praise by others is indicative of non-obviousness. I understand that Mr. Grafton had tried making a braided suture with a braid having just UHMW PE, but failed because the UHMW PE was too lubricious (Ex. 12 at 53-54). After he was unsuccessful with making a suture from just UHMW PE, Mr. Grafton thought of the idea of braiding UHMW PE yarns with PET yarns in direct intertwining contact (Ex. 12 at 53). When he explained his idea to Dr. Burkhart, who I understand is a surgeon, Dr. Burkhart described the idea as "killer" (Ex. 12 at 54). But Mr. Grafton's idea was patented in claims 1, 2 and 8 of the 446 patent. Thus, Dr Burkhart's praise for the idea was really a recognition of the importance of the 446 patent and indicative of the non-obviousness of at least claims 1, 2, and 8 of the 446 patent.

7. Claims 1, 2, 8, 9, and 12 of the 446 Patent Are Not Obvious Over the 688 Patent In Light Of The References Cited by Dr. Mukherjee

66. Based on (i) the scope and teachings of the 688 patent, the 802 patent, the DSM brochure, and the general state of the art referred to by Dr. Mukherjee; (ii) the differences between claim 1 of the 446 patent and the art cited by Dr. Mukherjee; (iii) the level of ordinary skill in the art; and (iv) the secondary considerations of non-obviousness, claim 1 of the 446 patent is non-obvious.

67. Claims 2 and 12 of the 446 patent recite the additional limitation that the suture of claim 1 "is attached to a needle" (Ex. 2 at 9:11-12). Because claims 2 and 12 contain all of the limitations of claim 1 plus an additional limitation, they are non-obvious for the same reasons as claim 1.

68. Claim 8 of the 446 patent recites that the “second set of yarns is PET” (Ex. 2 at 10:7-8), but is otherwise the same as claim 1. In order to show the obviousness of claim 8, the references must suggest (or motivate one of ordinary skill in the art to form) a suture having all of the limitations of claim 1 and the claimed second yarn being PET, as opposed to Nylon, PET, or aramid as recited in claim 1. The art relied upon by Dr. Mukherjee does not disclose the claimed second yarn as being PET for the reasons set forth above with respect to claim 1. Accordingly, except for my opinions regarding Nylon and aramid, my opinions described above with reference to the 688 patent and the other references apply to claim 8.

69. Claim 9 of the 446 patent is also non-obvious for the same reasons as claims 1 and for additional reasons. Claim 9 of the 446 patent recites that “the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent” (Ex. 2 at 10:9-11; 18-19). Dr. Mukherjee has pointed to nothing that discloses this limitation. Given this additional difference of claim 9 and the lack of any motivation to form a suture having this limitation, claim 9 is non-obvious for this additional reason.

C. Claims 1, 2, 8, 9, and 12 of The 446 Patent Are Not Anticipated By Chesterfield

70. Dr. Mukherjee opined that Chesterfield “discloses every limitation of the asserted claims” (Mukherjee at 14). I disagree. The 575 patent does not disclose many limitations of claims 1, 2, 8, 9, and 12 of the 446 Patent.

71. The 575 patent does not disclose to one of ordinary skill in the art a heterogeneous braid of the claimed yarns from the first-fiber forming materials with the second fiber-forming materials in direct intertwining contact. Further, the 575 patent does not teach a suture having a braid of PE (including UHMW PE) with PET, Nylon, or

aramid. I understand that in order for the 575 patent to anticipate the 446 patent claims, it must disclose every limitation of the 446 Patent claims (expressly or inherently) arranged in the same way as claimed in the 446 Patent claims. Because the 575 patent does not teach all of the limitations of the claimed invention arranged in the same way, it is my opinion that there is no anticipation.

72. In general, I disagree with Dr. Mukherjee because he picks and chooses different teachings of the 575 patent and combines them in a way that is not described in the 575 patent and then concludes that the 575 patent teaches the claimed invention. Basically, he forms the claimed invention by selecting teachings about a sternum closure device in the 575 patent and combining them with select teachings about a suture repair device in the 575 patent. But I disagree with his analysis because the 575 patent does not expressly or inherently describe the claimed invention. I address some of Dr. Mukherjee's specific points below.

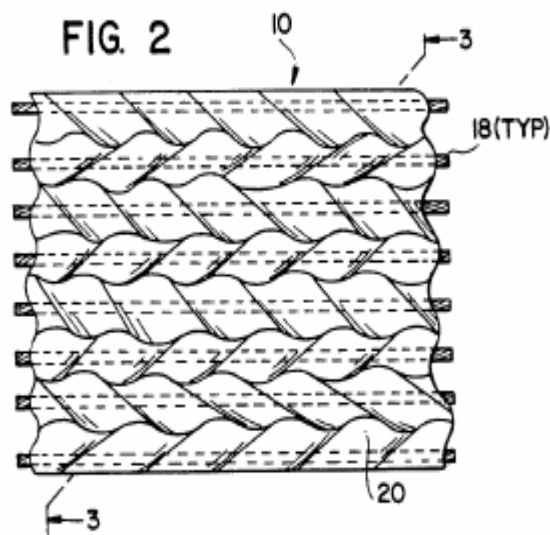
73. Dr. Mukherjee cites to column 3, lines 61-67, of Chesterfield as disclosing nylon or PET. I disagree. This citation does not refer to nylon or PET. In fact, column 3, lines 61-67, specifies that the material 20 is a "bioabsorbable polymeric material such as . . . polyester" (Ex. 6 at 3:63-67). Neither nylon nor PET are bioabsorbable polyesters; they are non-absorbable materials. Thus, column 3, lines 61-67 is not a disclosure of either PET or nylon.

74. Dr. Mukherjee also cites to column, 3, lines 61-67, of Chesterfield as disclosing nylon or PET braided with UHMW PE in a *suture*. But I disagree. The 575 patent at column, 3, lines 61-67, describes that fibers 20 are used in the outer structure in the *sternum closure ribbon 10*, not a suture. Thus, this citation to col. 3, lines 61-67 does

not teach nylon or PET braided in a suture, much less braided in direct intertwining contact with UHMW PE.

75. Dr. Mukherjee cites the filler yarns 20 of the *sternum closure device* as being braided with the UHMW PE in the *spiroid braid* of Fig. 7. But the filler yarns 20 are from a *sternum closure device* (Figs. 2 and 4) and the UHMW PE (to which he cites) is from a *spiroid braid* (Fig. 7). Thus, they are not braided in direct intertwining contact as required by the 446 patent claims.

76. Further, Chesterfield does not teach a heterogeneous braid for the braided fibers 20 in the sternum closure device 10 (below). Rather, Chesterfield teaches that the braided fibers 20 are in a homogeneous woven structure (Ex. 6 at 3:61-4:1, 4:39-47).



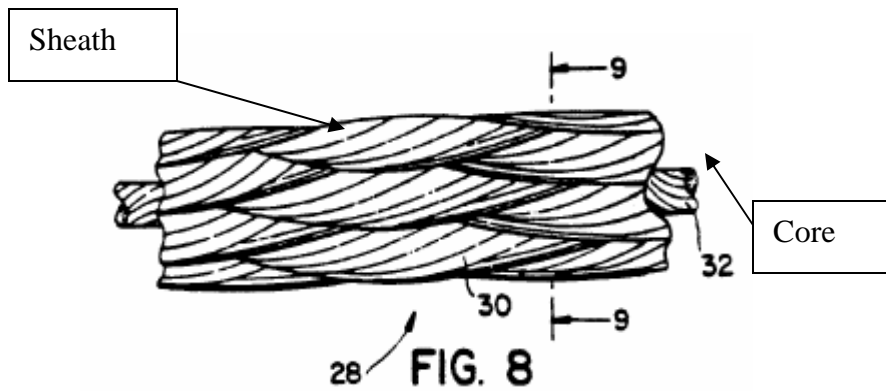
Therefore, his citation to Chesterfield's sternum closure device does not disclose nylon, aramid, or PET braided in direct intertwining contact with PE in a suture, as claimed in the 446 Patent.

77. Again, Dr. Mukherjee piecemeals two materials from two different structures to describe the heterogeneous braided suture as claimed in the 446 Patent. Specifically,

Dr. Mukherjee takes the UHMW PE from the core of the *hollow braid* of Figs. 8 and 9 and matches it with either the (1) bioabsorbable polyester of the *sternum closure device* or (2) the material of the *spiroid braid* of Fig. 7. This picking and choosing of two different materials from two different structures does not teach a single suture construction having the claimed first and second fiber forming materials braided in direct intertwining contact as claimed in the 446 Patent.

78. Dr. Mukherjee also cites to column 7, lines 59-60, as disclosing a heterogeneous braid with direct intertwining contact where one of the yarns is PE (Mukherjee at 14-16). But column 7, lines 59-60 of Chesterfield only describes PE in the core. The PE referred to in column 7, lines 59-60, is not in the sheath, is not described as braided with another material, is not described as braided with the claimed second fiber-forming materials (nylon, aramid, or PET), and is not described as braided in direct intertwining contact with the claimed second fiber-forming materials.

79. Dr. Mukherjee also cites to claims 11 and 12 of the 575 patent as disclosing nylon and polyester respectively braided in direct intertwining contact with UHMW PE in a heterogeneous suture braid as claimed in the 446 patent. I disagree. Claims 11 and 12 of the 575 patent refer to second non-absorbable fibers as being formed from either nylon or polyester. But claims 11 and 12 of Chesterfield do not specify how the second fibers are braided with the claimed first fibers. For example, Chesterfield claims 11 and 12 do not recite that the first and second fibers are braided in direct intertwining contact, as opposed to a core-sheath arrangement (like that described in Chesterfield Figs. 8, reproduced below, & 9), with the first fiber materials only in the core and the second fiber materials only in the sheath.



80. Further, claims 11 and 12 recite a “method for repairing split portions of body tissue comprising looping a flexible elongated member about the body tissue...” (Ex. 6 at 8:29-38; 60-65). It is my opinion that this refers to a method of using the sternum closure device, not a suture, because a sternum closure goes “about” the margins of tissue (Ex. 6 at Fig. 1) while a suture goes through tissue. Thus, claims 11 and 12 do not refer to a suture and therefore cannot teach all the limitations of the claims of the 446 Patent.

81. Dr. Mukherjee also cites to Chesterfield at column 4, lines 9-23, as disclosing the second fiber forming materials (PET, nylon, or aramid) braided in direct intertwining contact with the first-fiber forming materials (Mukherjee at 16). But that portion of Chesterfield does not explicitly mention nylon, aramid, or PET. Although, that citation does state that “[a]ny number of combinations of bioabsorbable yarns, filamentary or otherwise, and/or non-absorbable, and high strength filaments are contemplated” (Ex. 6 at 4:20-24), it does not disclose how these materials are selected or arranged, such that a person of ordinary skill in the art would understand that nylon, aramid, or PET are necessarily disclosed and arranged as claimed in the 446 patent. For example, it does not disclose PET, Nylon, or aramid braided in direct intertwining contact with UHMW PE, as claimed in the 446 Patent.

82. I understand that for any claimed limitation to be inherently disclosed, it must necessarily be disclosed. I see no reason why PET, nylon, or aramid is necessarily disclosed as being braided with UHMW PE in direct intertwining contact in a suture as claimed in the 446 Patent based on Dr. Mukherjee's citation to column 4 of the 575 patent. For example, Dr. Mukherjee provides no explanation as to why one of ordinary skill in the art finds that this statement discloses selecting either PET, nylon, or aramid from the universe of possible yarns. Nor does he provide an explanation of why only one yarn would be picked to be braided with PE in direct intertwining contact when the 575 patent refers to "any combination" of the universe of yarns and does not specify any particular braiding arrangement.

83. I note that when Arthrex was prosecuting an application, which ultimately issued as the 234 patent, Arthrex represented to the Patent & Trademark Office that Chesterfield "does not disclose an example of a braided sheath that includes a blend of both UHMWPE and polyester" (Ex. 13 at DMI041091).

84. Thus, Arthrex's patent counsel agreed with me when it was prosecuting its own patent application.

85. Also, claim 9 of the 446 patent is not anticipated by Chesterfield for the additional reason that Chesterfield does not describe the limitation of claim 9 that the "volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent."

D. If The Claims Of The 446 Patent Are Construed To Mean That “PE” Includes UHMW PE, Then The 446 Patent Is Non-obvious Over Burgess And i) Cohan; ii) The DSM Brochure; And/Or iii) The Harpell Patents

86. My below opinions assume that the claims of the 446 Patent are construed to mean that “PE” includes UHMW PE.

1. It Is My Opinion That Claims 1, 2, 8, 9 and 12 of the 446 Patent Are Not Invalid For Obviousness Over Burgess In View Of Cohan

87. Dr. Mukherjee states that claims 1, 2, 8, and 12 of the 446 Patent are invalid as obviousness over Burgess in view of Cohan. I disagree. Below I discuss the teachings of Burgess and Cohan to one of ordinary skill in the art between 1988 and 1992.

a) The Scope And Content Of Burgess

88. Burgess discloses fishing lines (Ex. 7 at 1), not suture or medical devices.

Burgess discusses certain desirable properties of a fishing line, but does not mention certain suture properties, such as knot security or knot strength (Ex. 7 at 1). Burgess does state that fishing lines “require... non-stretchability” (Ex. 7 at 1). Burgess states that “non-stretchability” is a fishing line requirement, not a preference (Ex. 7 at 1).

89. Burgess further discloses a fishing line that should have a “braided construction” (Ex. 7 at 1). Burgess discloses that some filaments are of “high tensile polythene thread” and other filaments are “polyester and/or nylon” (Ex. 7 at 1). But Burgess does not disclose what kind of “braided construction” he envisioned, how to construct the braid which he references, nor how to use the materials in the “braided construction” he references. For example, Burgess does not disclose whether the polythene thread should be in the core, whether it should be in the sheath alone, or in the sheath with another material. Nor does Burgess disclose whether the polyester and/or nylon alone

should be in the core, whether it should be in the sheath alone, or in the sheath with another material. At no point does Burgess state that the polythene can be in a sheath with another material such as nylon or polyester.

90. In fact, the Burgess disclosure is at most two double-spaced pages. Burgess has no drawings; Burgess provides no working detail or explanation whatever of the braided fishing-line construction which he references. Nor does he provide any description of how to make the “braided construction” to which he refers or the type of equipment that should be used to fabricate the “braided construction” for a fishing line.

91. Burgess discloses the use of high molecular weight polythene in a fishing line. However, one of ordinary skill in the art would know that high molecular weight polythene is a lubricious material with poor knot security and knot tie down characteristics. Burgess does not disclose how to overcome these characteristics of high molecular weight polythene. Notably, Mr. Grafton, former Arthrex employee and developer of FiberWire, also stated that UHMW PE was typically used for fishing line and did not have acceptable knot tie down characteristics for use in sutures (Ex. 14 at 1:14-20). Mr. Grafton also stated that the poor knot slippage of UHMW PE was due to its lubricity (Ex. 12 at 53). Thus, Burgess discloses high molecular weight polythene, which is known to be a lubricous material, but does not describe how to construct an acceptable suture with UHMW PE.

92. I disagree with Dr. Mukherjee about the scope and content of Burgess. Dr. Mukherjee states that “the Burgess application discloses every limitation of claim 1 of the ‘446 patent . . . except that Burgess is not a sterilized suture” (Mukherjee at 17). But Dr. Mukherjee does not provide any analysis as to where the claimed limitations are

found in Burgess. Nor does he explain why Burgess necessarily teaches the braid claimed in the 446 patent, as opposed to some other braid construction. Thus, I disagree with his reading of Burgess.

93. Dr. Mukherjee uses the prosecution history of the 446 patent to support his reading of Burgess. I disagree that the prosecution history supports his analysis. Dr. Mukherjee cites to the Examiner's statement that "Burgess discloses a fishing line of braided construction comprising filaments of polyethylene and filaments of polyester or nylon," and suggests that the Examiner stated that the "braided construction" of Burgess was the same as the claimed "heterogeneous braid" of yarns in "direct intertwining contact." But the Examiner never said this. Notably, the Examiner never stated that Burgess discloses the claimed "heterogeneous braid" of yarns in "direct intertwining contact." Rather, the Examiner only stated that Burgess disclosed a "braided construction," not any specific braided construction, and then concluded it would have been obvious in light of Burgess to form the claimed invention of then pending claims 21-24. Thus, contrary to Dr. Mukherjee's suggestion, the Examiner never stated that Burgess discloses a heterogeneous braid of UHMW PE and Polyester or nylon in "direct intertwining contact" as claimed in the 446 patent.

b) The Scope And Content Of Cohan

94. Cohan discusses the use of an ultra strong polyethylene fiber in an ophthalmic suture. According to Cohan, the "polyethylene fibers are monofilaments with a ribbon shape." It also describes three monofilaments made from nylon, polypropylene, and polyester. The Cohan article discusses testing each of these monofilaments. The testing results are summarized in Figs. 2-4 and Tables 1-3. Figure 2 shows that a continuous filament of polyethylene has a greater tensile strength at break than the

other materials in the figure and also breaks at a significantly lower elongation. Figure 3 compares the knot pull strength of four fibers and shows that the knot pull strength of PE is higher than the others. Figure 4 describes the results of knot holding strength testing and shows that when comparing the four materials using a knot sequence commonly used in surgery, PE fails at a lower value than the other materials. According to Figure 4, the knot holding strength of PE is lower for certain knot configurations because the PE slips, whereas each of the other three materials break at a higher strength value for these knot configurations.

95. Table 2 of Cohan summarizes knot holding strength for different knot configurations and for four materials. According to Table 2, when the knot configuration was 2=2, PE did not register a value because the knot holding strength was too low (the knot slipped) whereas each of the other three materials reached their knot holding strength without slipping. At the 3=2=1 and 4=1=1 configurations, the PE showed a lower knot holding strength (e.g. 0.35 GPa compared to 0.45, 0.60 & 0.55 at configuration 4=1=1), than the other three materials because, again, the PE was failing by slipping. This knot slippage is not desirable because it means that a knot will not hold. The authors noted that when they tested the PE with more complex (4=4 & 4=4=4) knots, the PE still slipped at 4=4. The PE did not reach its final knot holding strength until a 4=4=4 knot was used. This testing shows to one of ordinary skill in the art between 1988 and 1992 that PE monofilament did not have the knot holding strength of other commonly used monofilaments at the same knot configuration. Also, one of ordinary skill in the art would have known that minimizing the number of knots used to secure a suture in surgery was an important characteristic in suture development.

Therefore, one of ordinary skill in the art would have recognized that Cohan teaches away from using UHMW PE in a suture.

96. Cohan also describes clinical use of the PE monofilament suture. The article states that the PE suture spontaneously untied and at a rate more common than the other materials. The authors explained that this untying was a result of the high flexibility and low friction of the PE. According to the authors, two of the PE fibers acted like “tracks” allowing the third fiber to “slip.” The poor knot tying properties of these UHMW PE monofilaments are a property of the PE itself.

97. Also, Cohan describes the solution for PE’s lower knot holding strength was to tie more complex knots. Cohan does not mention or suggest forming a heterogeneous braid with PE to correct the problem. Thus, one of ordinary skill in the art would have recognized that Cohan teaches away from braiding UHMW PE in a suture.

98. Cohan shows Scanning Electron Micrographs (SEM) of the PE fibers. The SEM’s show lateral connections between the fibrils. The authors also noted in their clinical experience “the occasionally unraveling of microfilaments from the [PE] fiber, sometimes causing irritation until they were removed.” The authors do not explain the cause of the unraveling, or that the possible cause is the fibrils shown in Fig. 1. Further, the authors posit that the use of “gel-spinning” to synthesize the fibers may eliminate the unraveling. But they offer this only as a hypothesis not a proven solution. Because of this recognized, but unsolved problem, one of ordinary skill in the art between 1988 and 1992 would not have been motivated to use UHMW PE in sutures.

99. Cohan states that it was trying to design a suture that was stronger than multifilament silk suture but still has the handling properties of silk. The solution provided by the article is a monofilament PE that requires more complex knots.

100. Dr. Mukherjee makes several statements with respect to Cohan with which I disagree. For example, he states that Cohan teaches a suitable suture made of UHMW PE, and that it is superior. He misinterprets the test results in Table 2. He states that the suture made of UHMW PE had superior knot strength and knot security when compared to the other materials. But Table 2 of Cohan shows that PE had less knot holding strength and less knot security when using comparable knot configurations. In fact, the authors noted that the PE constructs had less knot security because they slipped and failed using certain commonly employed knot configurations.

101. I also disagree with Dr. Mukherjee's statement that Cohan describes a "superior" UMMW PE suture because Cohan's solution to the knot holding strength of UHMW PE was to tie more complex knots. One of ordinary skill in art would recognize this solution was not commercially acceptable to surgeons. A suture that requires a surgeon to tie more complex knots is simply not a "superior" suture.

102. I further disagree with Dr. Mukherjee's statement that Cohan describes a "superior" UHMW PE suture because the authors noted that PE spontaneously untied at a greater rate than the other materials during clinical studies. The unraveled PE led to irritation. Although Cohan posits the hypothesis that "gel-spinning" may eliminate the unraveling, this is an unproven solution to the problem. Thus, given these unresolved issues recognized by Cohan, I do not understand how Dr. Mukherjee opines that the monofilament PE suture of Cohan is a superior suture with superior knot security.

c) The Differences Between Burgess And Cohan And Claim 1 of the 446 Patent Are Significant

103. There are many differences between claim 1 of the 446 patent and the combination of Burgess and Cohan. These differences indicate the non-obviousness of claim 1 of the 446 patent.

104. Claim 1 of the 446 Patent claims a suture. Burgess only describes a fishing line.

105. Claim 1 of the 446 Patent claims a heterogeneous braid where at least one set of yarns from the first group is in direct intertwining contact with at least one yarn from the second group. Burgess does not teach this. In fact, Burgess is entirely silent on the construction of the fishing line or its method of assembly. Thus, Burgess does not teach the braid recited in claim 1 of the 446 Patent.

106. Also, because Burgess does not describe the braided construction he references and does not describe how to make it, Burgess does not enable one skilled in the art between 1988 and 1992 to make and use a suture of claim 1 of the 446 Patent. I do not understand how Dr. Mukherjee considers Burgess to be detailed enough to teach one of ordinary skill in the art in 1992 how to make and use the claimed heterogeneous braid of the 446 Patent, and at the same time opine that the 446 Patent, which is much more detailed than Burgess, does not enable one of skill in the art to make and use the invention claimed in the 446 Patent. Burgess simply does not describe any type of braiding construction, braiding equipment or any braid manufacturing or processing.

107. Likewise, Cohan does not teach the invention of claim 1 of the 446 Patent. Nor does Cohan fill in the gaps left by Burgess. Cohan does not teach a heterogeneous braided suture. Further, the Cohan article does not teach the materials recited in claim

1 of the 446 Patent, where at least one material from the claimed first-fiber group is in direct intertwining contact with a yarn from the claimed second-fiber group.

108. I note here that I disagree with Dr. Mukherjee's opinion that Cohan somehow demonstrates that Mr. Goodwin was incorrect in his response to the patent office when discussing Burgess (Mukherjee at 18). First, Dr. Mukherjee inaccurately paraphrases Mr. Goodwin's statements to the Patent Office. Dr. Mukherjee incorrectly characterizes Mr. Goodwin's statements as "if one were to make a product with high tensile polythene . . . it would be 'unsuitable for use as sutures'" (Mukherjee at 18). Mr. Goodwin never said this. Rather, he said that a medical designer following the teachings of Burgess on how to construct a fishing line with different design criteria than suture would inevitably design an unacceptable suture.

109. Secondly, contrary to Dr. Mukherjee's statements, Cohan shows that Mr. Goodwin was correct. Cohan describes that UHMW PE has poor knot holding strength, which means it is has poor knot strength and poor knot security. Thus, Mr. Goodwin's statements were accurate that knot security and knot strength are a concern and Burgess does not discuss how to address these issues. This is confirmed by Arthrex's 234 patent which explains that fishing line having UHMW PE "does not have acceptable knot tie down characteristics for use in surgical applications" (Ex. 14 at 1:13-20).

d) One of Ordinary Skill in the Art Would Not Have Been Motivated to Combine Burgess with Cohan to Form the Claimed Invention

110. One of ordinary skill in the art would not have been motivated to combine Burgess and Cohan between 1988 and 1992 to form the suture of claim 1 of the 446 Patent. There is no motivation in either Burgess or Cohan to combine them. Also, as

discussed below there is no motivation based on their teachings or the level of skill in the art for several reasons.

111. First, because of the significant differences between Burgess and Cohan and claim 1 of the 446 patent, one of ordinary skill in the art would not have been motivated between 1988 and 1992 to modify Burgess to form the claimed invention. For example, neither describes the claimed heterogeneous suture braid of claim 1 of the 446 Patent, and there is no motivation or suggestion to combine the references to form the claimed braided suture.

112. Second, because Burgess does not describe knot security or knot strength, one of ordinary skill in the art between 1988 and 1992 would not have been motivated to use the teachings of Burgess to make a suture. Knot security and knot strength are two important suture properties. Therefore, Burgess' discussion of different requirements for fishing line and failure to mention knot strength or knot security would cause one of ordinary skill in the art not to be motivated to use Burgess' teachings in designing a suture.

113. Third, Cohan recognizes that monofilament PE has lower knot holding strength and posits overcoming this problem by tying more complex knots. Burgess says nothing about knot holding strength or how to solve the issues raised by Cohan. Thus, one of ordinary skill in the art would not have been motivated to combine Burgess and Cohan to form the claimed invention because he would have focused on trying to resolve the knot holding strength issues raised by Cohan by tying different knots.

114. Fourth, Cohan teaches that monofilament UHMW PE had disadvantages including lower knot holding strength, requiring more complex knots, spontaneous

untying, and unraveling, leading to irritation. Given these problems with the UHMW PE monofilament in Cohan, one of ordinary skill in the art having read Cohan between 1988 and 1992 would not have been motivated to further pursue using UHMW PE without first solving these issues.

115. Fifth, even assuming that one of ordinary skill in the art would have been motivated to pursue the teachings of Cohan, Cohan teaches away from braiding. Cohan teaches trying to design a suture that was stronger than multifilament silk suture, but still had silk's handling properties by tying more complex knots. One of ordinary skill in the art between 1988 and 1992, who had read Cohan, would have focused on monofilaments, tying different types of knots, and eliminating unraveling, not braiding.

116. I have read Dr. Mukherjee's report and Dr. Mukherjee does not specify any motivation for combining the Burgess reference with the Cohan article. He also ignores the differences between the monofilament described in Cohan and the claimed invention of the 446 Patent and the problems noted by Cohan with UHMW PE. Thus, I disagree with his opinion.

117. I note that Dr. Mukherjee states that "it would have been obvious to a person of ordinary skill in the art, in February 1992, to use a heterogeneous braid, such as that disclosed in the Burgess application, for a suture" (Mukherjee at 18). I disagree for the reasons set forth above, but note that the general problem with this statement is that Burgess does not disclose any specific braid construction. Thus, one of ordinary skill in the art reading Burgess in 1992 would not have been able to just simply use a braid disclosed by Burgess as a suture, as Dr. Mukherjee suggests.

e) The Combination of Burgess & Cohan is Cumulative to References The Examiner Considered

118. Dr. Mukherjee relies on Burgess for his obviousness opinions. But Burgess was considered by the Examiner. Dr. Mukherjee's obviousness opinions with respect to Burgess appear to be based on the incorrect premise that the Examiner was not aware of a reference showing that UHMW PE could be used in a suture, and if he was, he would have combined it with Burgess to reject the 446 patent application claims. But the Examiner already considered a reference that explicitly discloses using UHMW PE in a suture (Ex. 15 at PCT application WO 86/00020 at DMI000150-179, e.g. Abstract and p. 8). Therefore, the Examiner considered Burgess and a reference disclosing the use of UHMW PE in a suture (Ex. 17 at DMI000596). Consequently, to the extent that Dr. Mukherjee's obviousness opinions rely on Burgess and other references showing UHMW PE in sutures, his opinions are based on information already considered and rejected by the Examiner. Thus, the Examiner's issuance of the 446 patent over these references confirms my opinions of non-obviousness.

f) Secondary Considerations of Non-obviousness

119. As explained above, the inventions of claims 1, 2, 8, 9, and 12 of the 446 patent have been commercially successful and have been praised by Arthrex. This indicates their non-obviousness.

g) Claims 1, 2, 8, 9, and 12 of the 446 Patent Are Not Obvious Over Burgess in light of Cohan

120. Based on (i) the scope and teachings of Burgess and Cohan; (ii) the differences between claim 1 of the 446 patent and Burgess and Cohan; (iii) the level of ordinary skill in the art; (iv) the secondary considerations of non-obviousness; and (v) Burgess and

Cohan being cumulative to the information considered by the Examiner, claim 1 of the 446 patent is non-obvious.

121. Claims 2 and 12 of the 446 patent recite the additional limitation that the suture of claim 1 “is attached to a needle” (Ex. 2 at 9:11-12). Because claims 2 and 12 contain all of the limitations of claim 1 plus an additional limitation, they are non-obvious for the same reasons as claim 1.

122. Claim 8 of the 446 patent recites that the “second set of yarns is PET” (Ex. 2 at 10:7-8), but is otherwise the same as claim 1. In order to show the obviousness of claim 8, the references must show a suture having all of the limitations of claim 1 and the claimed second yarn being PET, as opposed to Nylon, PET, or aramid as recited in claim 1. The art relied upon by Dr. Mukherjee does not disclose the claimed second yarn as being PET for the reasons set forth above with respect to claim 1. Accordingly, except for my opinions regarding Nylon and aramid, my opinions described above with reference to Burgess and Cohan apply to claim 8.

123. Claim 9 of the 446 patent is also non-obvious for the same reasons as claim 1 and for additional reasons. Claim 9 of the 446 patent recites that “the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent” (Ex. 2 at 10:9-11). Dr. Mukherjee has pointed to nothing that discloses this limitation. Given this additional difference of claim 9 and the lack of any motivation to form a suture having this limitation, claim 9 is non-obvious for this additional reason.

2. It Is My Opinion That Claims 1, 2, 8, 9, and 12 of the 446 Patent Are Not Obvious Over Burgess & The DSM Brochure

124. Claims 1, 2, 8, 9, and 12 of the 446 patent are not obvious over Burgess in light of the DSM brochure. I have described the scope and content of Burgess and the DSM

brochure above. Also, I have described the differences between Burgess and the DSM brochure and the sutures of claims 1, 2, 8, 9, and 12 above. Those discussions apply here as well.

a) One of Ordinary Skill in the Art Would Not Have Been Motivated to Combine Burgess with the DSM Brochure to Form Claim 1 of the 446 Patent

125. One of ordinary skill in the art from 1988-1992 would not have been motivated to combine Burgess and the DSM brochure to form the claimed invention of the 446 Patent for many reasons. There is no motivation to combine them in such a way so as to form the claimed suture of the 446 patent.

126. First, because of the significant differences between the invention claimed in the 446 patent and Burgess and the DSM brochure, one of ordinary skill in the art between 1988 and 1992 would not have been motivated to combine them to form the claimed invention. For example, because neither describes a heterogeneous braid of yarns in direct intertwining contact, as claimed in the 446 Patent, there is no motivation or suggestion to combine the references to form the claimed heterogeneous braid.

Burgess does not describe how to combine the polyester and/or nylon with UHMW PE. The DSM brochure does not describe combining yarns at all or how to construct any type of suture. Thus, because of the significant differences between the invention claimed in the 446 patent and these references and the lack of any guidance as to how or why to make a braid, there is no motivation or suggestion as to how to combine the UHMW PE with nylon and/or polyester to form a heterogeneous braid in direct intertwining contact as claimed in the 446 Patent.

127. Second, because Burgess does not describe knot security or knot strength and the DSM brochure touts the high knot strength of certain Dyneema fibers, one of

ordinary skill in the art between 1988 and 1992 would not have been motivated to use the teachings of the DSM brochure with the teachings of Burgess. One of ordinary skill in the art in 1992 would have been motivated to explore using just the UHMW PE fibers taught by the Dyneema brochure to take advantage of the touted knot strength. There is no discussion in either reference of how braiding affects knot strength. In my opinion, one of ordinary skill in the art would not have attempted to braid UHMW PE with nylon or PET based on these references because the resulting effect on knot strength was not known.

128. Third, one of ordinary skill in the art would not have been motivated to combine the DSM brochure and Burgess to form the claimed suture of the 446 patent because he would have known that the UHMW PE disclosed in the DSM brochure was lubricious and therefore would not provide good knot security. Neither the DSM brochure nor Burgess discuss how to address UHMW PE's lubricity and form a suitable suture. Thus, absent a teaching addressing this issue, one of ordinary skill in the art would not have been motivated to combine Burgess and the DSM brochure to arrive at the claimed invention.

129. I note that Dr. Mukherjee does not provide any motivation or suggestion to combine Burgess and the DSM brochure to form the claimed invention. Dr. Mukherjee opines that one of ordinary skill in the art in 1992 would have "been motivated to take the recommendation of the DSM brochure to use Dyneema in a suture application and to combine it in a braided suture with polyester/and or nylon, as in Burgess." But Burgess is not a "suture application." Therefore, even if one of ordinary skill in the art would have been motivated to use the Dyneema described in the DSM brochure in

“suture application,” it would not be with Burgess. Further, even if one was motivated to use the Dyneema with the teachings of Burgess, Burgess does not describe any braid construction. Therefore, there is no motivation or suggestion to form the claimed invention.

b) The Combination of Burgess & the DSM Brochure is Cumulative to References The Examiner Considered

130. Dr. Mukherjee’s obviousness opinions with respect to Burgess and the DSM Brochure appear to be based on the incorrect premise that the Examiner was not aware of a reference showing that UHMW PE could be used in a suture, and if he was, he would have combined it with Burgess to reject the 446 patent application. But, as described above with reference to Cohan, the Examiner already considered a reference that explicitly discloses using UHMW PE in a suture (Ex. 15 at PCT application WO 86/00020 at DMI000150-179, *e.g.* Abstract and p. 8). Thus, Burgess and the DSM Brochure are cumulative to the references considered by the Examiner, and the Examiner’s issuance of the 446 patent over these references confirms my opinions of non-obviousness.

c) Secondary Considerations of Non-obviousness

131. As explained above, the inventions of claims 1, 2, 8, 9, and 12 of the 446 patent are non-obvious and have been praised by Arthrex. This indicative of their non-obviousness.

d) Claims 1, 2, 8, 9, and 12 of the 446 Patent Are Not Obvious Over Burgess & the DSM Brochure

132. Based on (i) the scope and teachings of Burgess and the DSM brochure; (ii) the differences between claim 1 of the 446 patent and Burgess and the DSM brochure; (iii) the level of ordinary skill in the art; (iv) the secondary considerations of non-

obviousness; (v) and Burgess and the DSM brochure being cumulative to the information considered by the Examiner, claim 1 of the 446 patent is non-obvious.

133. Claims 2 and 12 of the 446 patent recite the additional limitation that the suture of claim 1 “is attached to a needle” (Ex. 2 at 9:11-12). Thus, claims 2 and 12 of the 446 patent are non-obvious for the same reasons as claim 1 of the 446 patent. Claim 8 of the 446 patent recites that the “second set of yarns is PET” (Ex. 2 at 10:7-8). As described above, neither Burgess nor the DSM brochure disclose PET braided as claimed. Thus, with this exception that claim 1 recites that the second fiber forming material could be nylon, aramid, or PET, my opinions described above with reference to Burgess and the DSM brochure apply to claim 8 as well, and it is non-obvious.

134. Claim 9 of the 446 patent are also non-obvious for the same reasons as claims 1 and for additional reasons. Claim 9 of the 446 patent recites that “the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent” (Ex. 2 at 10:9-11). Dr. Mukherjee has pointed to nothing that discloses this limitation. Given this additional difference of claim 9 and the lack of any motivation to form a suture having this limitation, claim 9 is for this additional reason non-obvious.

3. Claims 1, 2, 8, 9, and 12 of the 446 Patent Are not invalid For Obviousness Over Burgess and the Harpell Patents

a) The Scope and Content of Burgess & the Harpell patents

135. The scope and content of Burgess is discussed above. Below, I discuss the teachings of the Harpell patents to one of ordinary skill between 1988 and 1992. Because Dr. Mukherjee has not differentiated between the Harpell patents and they appear to be substantially the same, I refer to the 392 Harpell patent for convenience.

136. The Harpell patents teach that extended chain polyolefin fibers, such as those formed from polyethylene and polypropylene (Ex. 9 at 1:8-9), have two disadvantages. First, the Harpell patents describe extended chain polyolefin fibers as having “low transverse strengths, with a corresponding tendency of the fibers to fibrillate especially when subjected to abrasion or self-abrasion, particularly when twisted or processed into a fabric” (Ex. 9 at 1:29-32). Second, the Harpell patents state that extended chain polyolefin fibers “have poor adhesion to most matrix materials” (Ex. 9 at 1:38). According to the Harpell patents, these disadvantages “limit the usefulness of these fibers in composite structures” (Ex. 9 at 1:39).

137. In order to overcome these disadvantageous, the Harpell patent teaches coating the extended chain polyethylene or polypropylene fibers with a “polyethylene, polypropylene, ethylene copolymer or propylene copolymer” (Ex. 9 at 1:43-45). The Harpell patents teach that coating the fibers “reduces the tendency of the fibers to fibrillate, increases their transverse strength, enables the fibers to be used in composite structures alone or with a variety of matrix materials and achieves these results without any significant loss of the tenacity and modulus values for the fiber alone (Ex. 9 at 1:46-51).

**b) The Difference Between Burgess & The Harpell Patents
And Claim 1 of the 446 Patent**

138. The differences between claim 1 of the 446 patent and Burgess were discussed above. The Harpell patents are also different than claim 1 of the 446 patent. Claim 1 of the 446 patent claims a heterogeneous braid of yarns in direct intertwining contact. The Harpell patents do not disclose a heterogeneous braided suture, let alone direct intertwining contact of two dissimilar yarns. Claim 1 of the 446 patent claims a

heterogeneous braid of certain materials. The Harpell patents do not disclose a braid having the claimed first and second fiber-forming yarns. Thus, both the Burgess and Harpell references do not contain numerous features recited in the claims of the 446 patent.

c) One of Ordinary Skill in the Art Would Not Have Been Motivated to Combine Burgess with the Harpell patents to Form Claim 1 of the 446 Patent

139. There is no motivation or suggestion to modify either Burgess or the Harpell patents in such a way so as to form the suture of claim 1 of the 446 patent.

140. Given the significant differences between the references and claim 1 of the 446 Patent, one of ordinary skill in the art would not have been motivated to combine the references to form the claimed suture. Neither Burgess nor the Harpell patents describe how to braid the materials in direct intertwining contact as recited in claim 1 of the 446 patent. The Burgess reference offers no specificity about the construction of the braid other than to use the term "braid." This hollow disclosure does not motivate one of ordinary skill in the art to use it in combination with the Harpell patents. Consequently, there is nothing in these references to teach one of ordinary skill in the art to make the invention of claim 1 of the 446 patent.

141. One of ordinary skill in the art would not have been motivated to combine the Harpell patents and Burgess for the additional reason that neither of these references describe knot security or knot strength. Knot security and knot strength are two characteristics important to a suture developer. Therefore, because there is no mention of these important characteristics, one of ordinary skill in the art would not have been motivated to use them together to improve suture properties.

142. Also, one of ordinary skill in the art would not have been motivated to combine Burgess and the Harpell patents because the Harpell patents describe coating fibers to reduce fibrillation. The Harpell patents describe certain fibers and coating them in the range of 0.1% to 200% by weight of fiber in order to reduce fibrillation (Ex. 10 at 4:40-42). With respect to suture applications, the Harpell patents disclose that a “preferred coating amount is between about 10 and about 50%, by weight of fiber” (Ex. 10 at 4:44-45). Therefore, rather than forming the claimed suture, one of ordinary skill in the art having read the Harpell patents between 1988-1992 would have been motivated to apply different coatings, in various amounts, and in different ways, to different UHMW PE or extended chain polypropylene fibers to determine whether the fibrillations could be reduced, not to form braided heterogeneous sutures.

d) The Combination of Burgess & the Harpell Patents is Cumulative to References The Examiner Considered

143. Dr. Mukherjee’s obviousness opinions with respect to Burgess and the Harpell patents appear to be based on the incorrect premise that the Examiner was not aware of a reference showing that UHMW PE could be used in a suture, and if he was, he would have combined it with Burgess to reject the 446 patent application. But, as described above with reference to Cohan, the Examiner already considered a reference that explicitly discloses using UHMW PE in a suture (Ex. 15 at PCT application WO 86/00020 at DMI000150-179, e.g. Abstract and p. 8). Thus, Burgess and the Harpell patents are cumulative to the references considered by the Examiner, and the Examiner’s issuance of the 446 patent over these references confirms my opinions of non-obviousness.

e) Secondary Considerations of Non-obviousness

144. As explained above, the inventions of claims 1, 2, 8, 9, and 12 of the 446 patent are non-obvious and have been praised by Arthrex. This indicates their non-obviousness.

f) Claims 1, 2, 8, 9, and 12 of the 446 Patent Are Not Obvious Over Burgess & the Harpell Patents

145. Based on (i) the scope and teachings of Burgess and the Harpell patents; (ii) the differences between claim 1 of the 446 patent and Burgess and the Harpell patents; (iii) the level of ordinary skill in the art; (iv) the secondary considerations of non-obviousness; and (v) Burgess and the Harpell patents being cumulative to the information considered by the Examiner, claim 1 of the 446 patent is non-obviousness.

146. Claims 2 and 12 of the 446 patent recite the additional limitation that the suture of claim 1 “is attached to a needle” (Ex. 2 at 9:11-12). Thus, claims 2 and 12 of the 446 patent are non-obvious for the same reasons as claim 1 of the 446 patent.

147. Claim 8 of the 446 patent recites that the “second set of yarns is PET” (Ex. 2 at 10:7-8). As described above, neither Burgess nor the Harpell patents disclose PET braided as claimed. Thus, with this exception that claim 1 recites that the second fiber forming material could be nylon, aramid, or PET, my opinions described above with reference to Burgess and the Harpell patents apply to claim 8 as well, and it is non-obvious.

148. Claim 9 of the 446 patent is also non-obvious for the same reasons as claim 1 and for additional reasons. Claim 9 of the 446 patent recites that “the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent” (Ex. 2 at 10:9-11). Dr. Mukherjee has pointed to nothing that discloses this

limitation. Given this additional difference of claim 9 and the lack of any motivation to form a suture having this limitation, claim 9 is for this additional reason non-obvious.

VII. It Is My Opinion That All of the Claims of the 446 Patent Are Not Invalid For Failing To Satisfy The Written Description & Enablement Requirements

A. The 446 Patent is Not Invalid for Failing to Satisfy the Written Description Standard

149. Dr. Mukherjee opines that all of the claims of the 446 Patent are invalid for failing to satisfy the written description standard. According to Dr. Mukherjee, the 446 Patent “does not reasonably convey to one of ordinary skill in the art that the inventors had possession of UHMWPE” (Mukherjee at 22). Since this is the only issue that Dr. Mukherjee has raised with respect to written description, it is the only one that I address. I disagree with his opinion. The 446 Patent does reasonably convey to one of skill in the art that the inventors had possession of the claimed suture with UHMW PE as the first-fiber forming material.

150. My opinion is supported by the 446 Patent’s text. The 446 Patent specifically claims “PE.” Further, the 446 Patent expressly describes “polyethylene (PE)” (Ex. 2 at 4:27,30). One of skill in the art would have known that “PE” means “polyethylene” and means all polymers made from ethylene. PE is the generic name for all types of PE, including UHMW PE. In 1987, the Encyclopedia of Polymer Science and Engineering 2nd edition volume 10 recognized polyethylene as the “common (source-based)” name for all polymers made from ethylene (Ex. 18). Further, the IUPAC officially recognized that PE is the accepted abbreviation for all types of PE (Ex. 19). Thus, one of skill in the art would have known that “PE” or “polyethylene” as used in the 446 Patent means all polymers from ethylene including UHMW PE.

151. The 446 Patent's description of PE is consistent with all types of PE. The 446 Patent states that in a preferred embodiment the first set of yarns act as lubricating yarns (Ex. 2 at 4:11-12). PE including UHMW PE is a lubricious yarn (Ex. 12 at 52-53). Cohan shows that one of skill in the art would have known that UHMW PE is a lubricious material because the UHMW PE used in the Cohan article slipped and required complex knot configurations in order to evaluate the material's knot hold strength. Also, the 446 Patent states that the first set of yarns may be derived from "non-absorbable polymers." PE including UHMW PE is a non-absorbable polymer. The 446 Patent also describes the first set of yarns as being made from fiber forming materials (Ex. 2 at 4:30-32). PE including UHMW PE is a fiber forming material. Therefore, the 446 Patent's description of PE is consistent with the meaning of PE and does not exclude UHMW PE.

152. My opinion that "PE" as used in the 446 Patent includes UHMW PE is supported by Arthrex's use of the term "polyethylene." I note that Arthrex described the UHMW PE used in FiberWire and other sutures as "polyethylene" without specifically calling out that it is UHMW PE (Ex. 20 at ARM002188-89; Ex. 21 at ARM02184-87; Ex. 22 at DMI Ex. 343). Also, I note that Cohan refers to ultrastrong polyethylene in the first instance but thereafter Cohan uses the terms ultrastrong polyethylene and polyethylene interchangeably to describe the suture materials. Further, my opinion that one of skill in the art would understand PE to include UHMW PE is confirmed by the DSM brochure. The brochure teaches that "polyethylene" properties cover the range from 1 N/tex specific strength and 25 N/tex specific modulus to 3.5 N/tex specific strength and 150 N/tex specific modulus. It also notes that Dyneema SK60 falls within this range at 2.7

N/tex and 90 N/tex. Thus, the DSM brochure refers to UHMW PE as polyethylene, and those skilled in the art do in fact refer to UHMW PE as polyethylene, just as the inventors did in the 446 Patent.

153. My opinion is further supported by the prosecution history of the 446 patent. Burgess discloses high molecular weight polythene (Ex. 7 at 1:13-14). During the prosecution history, Mr. Goodwin referred to the high molecular weight polythene disclosed in Burgess generically as “polythene,” which is the English term for polyethylene (Ex. 17 at DMI000595). Likewise, the Examiner twice referred to the high molecular weight polythene disclosed in Burgess generically as “polythene” (Ex. 17 at DMI000601). Notably, both the Examiner and the applicants referred to high molecular weight polythene by its generic or common, source-based name.

154. I disagree with Dr. Mukherjee that PE does not include UHMW PE to one of ordinary skill unless UHMW PE is specifically named. This statement makes no sense. It assumes that the well-accepted definition of PE is wrong and excludes UHMW PE. I know of no change in the well-accepted scientific naming conventions. While some authors may specifically refer to UHMW PE, my experience is that they do so when they want to emphasize the characteristics of UHMW PE as compared to PE. Here, the inventors of the 446 Patent had no reason to specifically refer to UHMW PE. PE was referred to as being lubricous. UHMW PE is lubricous. Therefore, there was no particular reason for the inventors to recite both PE and UHMW PE. Notably, the inventors referred to other materials such as nylon, aramid, PET, PTFE, PETFE, FEP, and PP generically as well. Therefore, the term PE was not treated any differently than the other materials. I note that Dr. Mukherjee does not read any other generic terms to

be limited to a certain range of the generic material. Further, Dr. Mukherjee equates the generic term “polypropylene” with a specific polypropylene, hard elastic polypropylene in the 688 patent. Thus, Dr. Mukherjee appears to read the generic term PE as limited, but not the other generic materials named in the 446 patent.

155. Dr. Mukherjee also states that the UHMW PE is not disclosed in the 446 Patent because PE is described in the 446 Patent as being “weak” which he states is inconsistent with UHMW PE (Mukherjee at 23). I disagree with both assertions. First, I disagree that the 446 Patent describes the first set of yarns being “weak.” The 446 Patent never describes the first fiber-forming yarns as “weak.” Instead, the 446 Patent, in one embodiment, describes the first set of yarns as lubricating yarns to “improve the overall pliability or compliance and surface lubricity of the heterogeneous braid” (Ex. 2 at 4:12-14). Dr. Mukherjee’s statement that the first set of yarns are described as being too weak is just incorrect. Notably, in the background of the 446 patent it describes a “highly pliable braid” made from “highly lubricous polymers” in a “traditional manner” as being “relatively weak and unusable” in most cases (Ex. 2 at 2:22-25). But this is not a description of the highly lubricous *material* as “weak.” Rather, it is a description of a certain *braid* – a *highly pliable braid* of just highly lubricous material -- as being weak, which is what one of ordinary skill would expect, because the material will likely slip (Ex. 8). I understand that Mr. Grafton constructed a braid of UHMW PE and had this very problem (Ex. 12. at 53-54).

156. Dr. Mukherjee’s opinion appears to be based on a misunderstanding of the invention described in the 446 Patent. He appears to equate lubricity with weakness and reads the 446 Patent, as describing braiding a weak yarn with a strong yarn. But

this is incorrect. The 446 Patent teaches, among other things, that a lubricious yarn can be braided with another yarn of different properties (e.g., different lubricity, strength) to yield a braid that benefits from the lubricity of the first material and the strength of the second material. One of skill in the art, reading the 446 Patent, would understand that a braid of UHMW PE and PET would benefit from the lubricity of the UHMWPE and the strength of the PET. Dr. Mukherjee appears to assume that because in some embodiments the 446 Patent describes the first set of yarns as being for lubricity and the second set of yarns being for adding strength, that the first set of yarns must be weak. That is not stated in the 446 Patent. Nor would one of skill in the art read “weakness” into the 446 Patent.

157. I also disagree with Dr. Mukherjee’s assertion that UHMW PE is not “weak.” Although Dr. Mukherjee refers to yarns as being “weak,” he does not describe in what sense they are weak. Thus, I am not sure what he means by weak. But, I note that Cohan described the tendency of monofilament UHMW PE to slip and the need for more complex knots when tying UHMW PE. In that sense, UHMW PE could be considered weak. I note that Arthrex made similar statements when applying for its own patent (Ex. 14 at 1:13-20). Arthrex reported in its 234 patent that UHMW PE “does not have acceptable knot tie down characteristics for use in surgical applications” (Ex. 14 at 1:20-21). Thus, with respect to knot hold, knot tie, and knot security UHMW PE may be considered “weak.”

B. It Is My Opinion That 446 Patent Claims Are Not Invalid For Failing To Satisfy The Enablement Requirement

158. Dr. Mukherjee opines that when “viewed from the perspective of a person skilled in the art in February 1992, the 446 Patent does not teach a person how to make and

use a surgical suture including UHMWPE without having to resort to undue experimentation (Mukherjee at 25). I disagree. It is my opinion that the 446 Patent does teach a person of skill in the art in 1992 how to make and use the claimed surgical suture without having to resort to undue experimentation.

159. I note that Dr. Mukherjee only discusses whether a person of skill in the art could make the invention, and he does not describe whether they could “use” the invention. Therefore, I will only address the issue of making. For the reasons explained above, I disagree with Dr. Mukherjee regarding whether the 446 Patent disclosed UHMW PE to one of skill in the art. The 446 Patent describes how to make the claimed suture without undue experimentation. The 446 Patent states that the “heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures” (Ex. 2 at 4:60-62). The 446 Patent also describes a “plan view” of a yarn carrier layout for a carrier braiding machine for braiding (Ex. 2 at Fig. 1 and 4: 63-66). The 446 Patent then describes how to make a braid of two yarns by moving the braiding machine carriers (Ex. 2 at 4:67-5:26) and forming a braid that is in direct intertwining contact. The yarns claimed in the 446 Patent, including UHMW PE, can be braided on a conventional carrier braiding machine described in the 446 Patent. One of ordinary skill in the art in 1992 would have known after reading the 446 Patent how to braid UHMW PE with either nylon, aramid, or PET to form the claimed invention. My opinion is supported by Pearsalls, I note that Pearsalls makes FiberWire by braiding UHMW PE on a conventional braiding machine with PET.

160. The 446 Patent also provides specific guidance on manufacturing certain preferred embodiments. The 446 Patent notes that “yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal” (Ex. 2 at 5:50-52). According to the 446 Patent, the “equilibration of yarn elongation may prevent irregularities, for example, core popping” (Ex. 2 at 5:53-54). Also, the 446 Patent advises that the “number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g., the tendency of the core popping and overall braid smoothness” (Ex. 2 at 5:56-61). Adjusting braiding tension is a routine, common practice to one of skill in the art and something that is generally adjusted when constructing any braids. Thus, with this guidance provided by the 446 Patent one of skill in the art could have made a braid of UHMW PE with PET, aramid, or nylon.

161. Further, the 446 Patent describes two preferred embodiments. In the first, it discloses that a braid of 70 denier PET and 110 denier PTFE (Ex. 2 at 7:38-39). It also discloses that for that braid a 32 pick gear with a spring tension of 0.009” for the PET carriers and no spring tension with the PTFE carriers (Ex. 2 at 7:49-50). Also, it discloses a second embodiment of 75.5% PET and 24.5% PTFE with the same spring tension. Thus, the 446 Patent clearly advised one of skill in the art---what he already knew—to adjust the yarn tension when braiding to accommodate for the different yarn properties, including elongation characteristics.

162. The 446 Patent also describes several other conventional suture manufacturing processes that were well known to one of skill in the art in 1992, including,

scouring to remove machine oils and lubricants, stretching “*preferably*” at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns, annealing to improve dimensional stability, coating, and sterilization (Ex. 2 at 5:61-6:30). All of these general techniques were known to one of skill in the art in 1992. They were employed to make sutures. Based on the teachings set forth in the 446 patent, one of skill in the art could easily have adapted the known braiding techniques to braid UHMW PE with PET, nylon, or aramid to form the claimed invention without undue experimentation.

163. Dr. Mukherjee appears to provide two reasons why one of skill in the art in 1992 could not after reading the 446 Patent make a braid of UHMW PE with either nylon, PET, or aramid. He states that “UHMWPE is known to be extremely strong and to have low elongation” and that “[t]hese specialized properties must be taken into account when including UHMWPE in a braided structure as they will have an effect on the manufacturing process” (Mukherjee at 26). He also states that because “UHMWPE has such low elongation ... [it] presents certain tensioning problems” (Mukherjee at 26). But Dr. Mukherjee does not describe what those “tensioning problems” are; why they are any different than braiding any two materials whose elongations do not match; and why it is beyond the routine skill in the art to adjust the braiding machine (e.g., adjust the braid tensions of the different yarns) to compensate for the differences in elongation. In any event, the 446 Patent specifically disclosed braiding and adjusting the “yarn tension” to compensate for different material elongation. Thus, the 446 Patent specifically addresses the “elongation” issue that Dr. Mukherjee refers to and describes how to solve it. A person of skill in the art would know that when operating a braiding

machine, the tension of the yarns has to be adjusted to compensate for the elongation of the yarns. Braiding yarns with conventional braiders was well-known in 1992. There is nothing peculiar about braiding UHMW PE that would not have been known to the person of ordinary skill. It was within the routine work of a person of skill to adjust braiding tension.

164. My opinion is supported by the testimony of Mr. Hallet from Pearsalls. He testified that Pearsalls uses all known conventional equipment to braid UHMW PE. For example, Pearsalls has had the Hubourns braider that it uses to make FiberWire for about 55 years (Ex. 23 at 71:8-12). Further, Mr. Hallet described the braiding of FiberWire on conventional carrier braiding machines and adjusting the tension based on the yarns (Ex. 23 at 63:5-70:10). My opinion is further supported by the testimony of Arthrex's manufacturing witness, Mr. Dreyfuss, who said that, when Arthrex began developing FiberWire™, braiding the UHMW PE required only "normal development" and was done with "ordinary" braiding techniques.⁵ Mr. Hallet testified that the tension had to be adjusted for various size FiberWire. That comports with my understanding of what was known to one of skill in the art in 1992 and why the 446 Patent would not need to specifically disclose braiding parameters specific to a certain size UHMW PE to be braided with another specific material on a specific machine.

⁵ [21:13 Q. When Arthrex began developing the FiberWire
 21:14 suture, did it have any problems braiding the ultra high
 21:15 molecular weight polyethylene?
 21:16 A. I'm sorry; could you read that back?
 21:17 (The requested portion of the record was read.)
 21:18 A. Not that I'm aware of.
 21:19 Q. It didn't -- The ultra high molecular weight
 21:20 polyethylene didn't require any special braiding
 21:21 techniques to produce a suture?
 21:22 A. Nothing out of the ordinary.
 21:23 Q. What does that mean?
 21:24 A. Normal development. (Ex. 24)

165. To the extent that Dr. Mukherjee is stating that the 446 Patent should have disclosed more particular details, I disagree because such details are manufacturing details related to making a commercial product that I understand need not be disclosed. For example, providing a specific braiding tension is somewhat meaningless because it is so specific. It is dependent on the type of machine, the number of yarns, the material of the yarns being braided, the size of the yarns, the denier of the yarns and other factors. There are many variables in setting the braiding tension that persons skilled in the art are familiar with that there was no reason for the 446 Patent to specifically disclose a specific braiding tension.

166. Dr. Mukherjee also opines that the one of skill in the art could not after reading the 446 patent make the claimed invention with UHMW PE because "UHMW PE reacts differently to heat than any of the disclosed second fiber-forming materials" which affects the braid's reaction to hot stretching and the 446 Patent does not advise whether hot stretching is necessary when using UHMWPE. I do not fully understand Dr. Mukherjee's opinion, so I am not able to respond. First of all, he does not define "hot stretching" so it is not clear what he means by the term. Further, it is not clear whether he believes that hot stretching a braid of UHMW PE is necessary, unnecessary, or necessary under certain parameters. Nor does he sufficiently identify what disclosure is allegedly missing from the 446 Patent so that, according to his opinion, one of skill in the art could not make the claimed suture in the 446 patent without undue experimentation.

167. Also, I note that Arthrex has a patent claiming sutures that claims a cover formed of a plurality of braided fibers which include UHMW PE (Ex. 14 at 3:13-17). I note that

Arthrex's patent provides no description of how to make a suture and certainly no description of what Dr. Mukherjee contends is absent from the 446 Patent. For example, Arthrex's 234 patent discloses two suture braids made on 16 and 12 carrier braiders with polyester and Dyneema, but does not disclose any braiding tensions, whether hot stretching is needed, or what temperatures at which to conduct any stretching, or how UHMW PE reacts to heat. If Arthrex's patent satisfies the enablement standard, I am not sure why the 446 Patent does not.

VIII. The Inventors Reduced the Claimed Invention to Practice

168. Generally, I understand that in order for a claimed invention to be actually reduced to practice, the invention must have been made and evaluated so that the inventors knew that it would work for its intended purpose.

169. I have reviewed Dr. Steckel's deposition transcript, Dr. Jamiolkowski's testimony, and Dr. Steckel's lab notebooks. It is my opinion that the inventors had made and tested a braided suture that was suitable for its intended purpose and had proved the concept of the invention at least as early as February 1989 and December 1989. I understand from Dr. Steckel's testimony that he referred to some of the work that led to the 446 patent as "Composite Braid Evaluation" or "CBE" (Ex. 25 at 135:1-21).

170. Dr. Steckel's notebook describes conception of the claimed invention at least as early as June 6, 1988 (Ex. 26 at DMI002617). Dr. Steckel describes his idea as "[a] preliminary evaluation of composite braids, *i.e.*, braided sutures constructed of two or more fiber types designed to realize the beneficial properties of each polymer" (Ex. 26 at DMI002617). He further states that the composite sutures to be evaluated included carrier blended "PET/PTFE" and "PET/PP" yarns in which blending occurs when two different yarns reside on different carriers during the braiding operation. (Ex. 26 at

DMI002617). Thus, at least as early as June 6, 1988, he had described the broad concept of a heterogeneous braided suture with two yarns in direct intertwining contact and provided two specific examples of braiding PET/PTFE and PET/PP (see *also* Ex. 27 at 99:7-25; 100:20-23; 102:10-17; 127:12-21; Ex. 25 at 159:6-23; 160:17-22; 161:4-10).

171. Dr. Steckel's notebook and testimony confirm that he built a suture braid as claimed in the 446 patent at least as early as June 6, 1988 (Ex. 26 at DMI002618; Ex. 27 at 127:12-128:21; Ex. 25 at 218:21-25). For example, Dr. Steckel built the CBE-15 prototype on June 6, 1988 with a carrier braider ("CB") (Ex. 26 at DMI002618). The CBE-15 braid was made from braid of 51% PET and 49% PTFE by volume (Ex. 26 at DMI002618). The yarns used to construct the CBE-15 braid are specified on page DMI002619 of Dr. Steckel's notebook (Ex. 26 at DMI002619). In June 1988, Dr. Steckel performed basic suture testing on CBE-15 including straight tensile and knot tensile testing (Ex. 25 at 219-220). Thus, at least as early as June 6, 1988, Dr. Steckel had conceived of the idea of braiding two materials, of the type claimed in the 446 patent, in direct intertwining contact to form a suture and had made a suture having these characteristics.

172. Dr. Steckel's notebook describes prototypes that he had constructed and tested as least as early as February 2, 1989 (Ex. 26 at DMI002635-38; Ex. 25 at 220-221). He had constructed PET/PTFE carrier braided sutures designated as CBE-15 having PET and PTFE yarns which were carrier braided in direct intertwining contact (Ex. 26 at DMI2635-36; Ex. 25 at 222-223). Dr. Steckel testified that "full characterization" of the braids had been completed at least as early as February 1989 (Ex. 25 at 218-219). His

notebook describes various testing that he performed on the braided sutures (Ex. 26 at DMI002637; Ex. 25 at 222).

173. Dr. Steckel had constructed and evaluated a suture that is within the scope of claims 1, 8, and 9 of the 446 patent at least as early as February 1989 (except it was not sterile). He had built a "heterogeneous suture" of PTFE and PET yarns. The PTFE and PET yarns were "continuous and discrete yarns" as claimed in the 446 patent (Ex. 2 at 8:65). They were also in "direct intertwining contact" because they were carrier braided (Ex. 2 at 8:67). The PTFE yarns were a "plurality of filaments of a first fiber-forming material," and the PET yarns were "a plurality of filaments of a second fiber-forming material" as claimed (Ex. 2 at 9:1-8). The volume fraction of the PTFE, the lubricating yarn, was 51% by volume (Ex. 26 at DMI002636). Further, Dr. Steckel had tested and evaluated the sutures. Therefore, he had reduced the sutures of claims 1, 8, and 9 to practice at least as early as February 1989.

174. I also note that Dr. Steckel built and tested prototypes in December 1989 (Ex. 26 at DMI2665-67). These prototypes were carrier blends of PTFE and PET yarns that were braided in direct intertwining contact (Ex. 26 at DMI2665). The specific braiding sequence is shown in Dr. Steckel's notebook (Ex. 26 at DMI2665). Similar to the prior PTFE/PET braids, these braids are also within the scope of claims 1, 8 and 9 of the 446 patent. Dr. Steckel evaluated the December 1989 prototypes and noted that the prototypes offered "exceptional handling properties for a braided suture" (Ex. 26 at DMI002665; Ex. 25 at 235:1-7). He also found that these prototypes "ranked better" in "handling properties" and knot-tie down relative to silk and Ethibond (Ex. 26 at DMI002666; Ex. 25 at 236:1-12). As he explained, the bending modulus of the

composite PTFE/PET suture braid was lower than silk and Ethibond (Ex. 26 at DMI002666-67). This means that the PTFE/PET braid was more flexible than silk and Ethibond. Dr. Steckel further noted that the intrinsic tensile and knot strength of the composite braid were 87 ksi. and 48 ksi. respectively. Based on Dr. Steckel's construction and evaluations, it is my opinion that Dr. Steckel had reduced to practice the claimed invention at least as early December 1989.

175. Dr. Mukherjee has opined that the inventors of the 446 patent did not actually reduce the invention to practice in February 1989 or prior to the February 19, 1992 filing date of the application. I disagree. The inventors had constructed a suture that they knew would work for its intended purpose.

176. Dr. Mukherjee opines that the inventors never actually reduced the claimed invention to practice because they did not construct a "sterile" suture (Mukherjee at 27-28). I first note that Dr. Mukherjee points to no specific testimony that says all of Dr. Steckel's braid constructions were not sterile. Dr. Mukherjee states that there was no reduction to practice because sterilization, generally, "*can* have a substantial effect on the braid properties" (Mukherjee at 28). But Dr. Mukherjee recognizes that this is only a possibility, not a fact. Also, Dr. Mukherjee provides no basis that this statement applies to any of the materials listed in the 446 patent. Further, he does not explain what effect he is referring to or under what conditions such effects may happen. Thus, even if the braids constructed by Dr. Steckel were not sterile, it is my opinion that the inventors had reduced the claimed invention to practice because the inventors had constructed and tested the claimed suture and knew that it would work as a suture for its intended purpose.

177. I also disagree with Dr. Mukherjee that sterilization was needed to reduce the claimed invention to practice because sterilization of medical devices including sutures were known processes that date well before the inventors work in 1988. The typical sterilization processes are gamma sterilization and ethylene oxide. Notably, the 446 Patent refers to both types of sterilization (Ex. 2 at 6:21-29). One of ordinary skill in the art would have been aware of both methods of sterilization and the parameters for sterilizing sutures and the materials claimed in the 446 patent. Further, one of ordinary skill in the art between 1988 and 1992 would have known that sterilization under normal conditions would not have had any substantial affect on braid properties, other than sterilization. Thus, there was no need for the 446 patent inventors to sterilize the sutures that they had constructed in order to show that they would work for their intended purpose and to prove the concept of their invention.

178. I further disagree with Dr. Mukherjee that sterilization was needed to reduce the claimed invention to practice because typically sterilization is done for product commercialization, not proof of concept. A suture designer would generally not sterilize his work unless it was to be tested in the body, or it involved product commercialization. Sterilization is basically a commercialization step that was not needed here to prove the concept of the invention claimed in the 446 patent. Requiring the inventor to sterilize the braided suture constructs would basically require him to make a commercial product and sterilize it in its packaging because typically sutures are sterilized in the packaging. In reality, suture designers do not sterilize suture designs to prove the concept unless the designs have something particular to do with sterilization. Here, the focus was on suture properties, and biological testing was not needed.

179. My opinion is supported by Mr. Grafton's deposition testimony concerning the development of the FiberWire product. Mr. Grafton testified that, after Arthrex tested the prototype suture braid of UHMW PE and PET, Arthrex believed it would work as a suture (Ex. 12 at 57). Although Mr. Grafton was not sure whether the sutures he tested were sterile or nonsterile (and I know of nothing indicating they were sterile), Mr. Grafton testified that sterilization would not be necessary at this stage of development, because it was only the mechanical features of the suture being tested, not the bio-burden levels (Ex. 12 at 60). Thus, Mr. Grafton's testimony supports my opinion that sterilization is typically not needed to prove the mechanical properties of a braided suture.

180. Dr. Mukherjee's testimony is contradicted by Arthrex's and Pearsall's own practices. I understand that Arthrex tested unsterile sutures when it tested coated and uncoated samples to show that FiberWire's coating has an effect on FiberWire's lubricity (Ex. 12 at 149). Arthrex's engineer who coordinated that testing was aware of the known sterilization techniques (Ex. 12 at 97). He must not have thought that sterilization could have a "substantial effect" on the braid properties, as suggested by Dr. Mukherjee, because otherwise he would have tested sterile sutures. If sterilization could have a "substantial effect" on the braid properties as Dr. Mukherjee suggests, then this casts doubt on the reliability of Arthrex's test results. Also, Pearsalls issued certificates of conformity on the braids that they made for Arthrex's FiberWire that describe certain suture properties such as knot strength. Arthrex has submitted these documents to the FDA. But Pearsalls does not sterilize sutures.

181. Dr. Mukherjee also opines that the 446 invention was not actually reduced to practice because there were “technical problems with the invention” (Mukherjee at 28-30). Dr. Mukherjee describes these problems as “core popping and braid looseness” (Mukherjee at 28). I disagree.

182. I first note that Dr. Mukherjee appears to take Dr. Steckel’s “braid looseness” and “core popping” comments out of context. For example, Dr. Steckel testified that the CBE-15 suture braid has been made on June 6, 1988, and there is no core popping or braid looseness documented with respect to that construction. Rather, the only documented braid construction “issues” with respect to the June prototypes involved yarn blended prototypes, not the carrier blended prototypes, such as CBE-0015 (Ex. 26 at DMI02620). Further, there is no documented “core popping” or “braid looseness” with respect to the braids constructed and tested in December 1989. Thus, contrary to Dr. Mukherjee’s suggestions Dr. Steckel had constructed PET/PTFE braids that did not have any “core popping” or “braid looseness” that was significant enough to document. Although Dr. Steckel did comment that the sutures evaluated in February 1989 had some “core popping” and “braid looseness,” these were “infrequent” issues (Ex. 25 at 227-229). Most significantly, they did not prevent Dr. Steckel from constructing and evaluating the braids (Ex. 25 at 227-229). Anyway, only part of the braid that he constructed had core popping or braid looseness. Thus, the part that did not coupled with the other prototypes was more than sufficient to show that his sutures would work for their intended purpose. As Dr. Steckel stated, although certain prototypes had core popping and braid looseness, these issues did not prevent him from making and evaluating the suture and its properties (Ex. 25 at 228). For example, he did not have to

make 100 meters of perfect suture to prove that the suture would work for its intended purpose. It was more than sufficient to have some portion of the 100 meters that did not have core popping and braid looseness to show that he had built a suture that could work for its intended purpose (Ex. 25 at 229-230). For example, Dr. Steckel concluded that the December 1989 prototypes had “exceptional handling properties” (Ex. 26 at DMI002665). If core popping and braid looseness was as big a problem as Dr. Mukherjee suggests, then Dr. Steckel could not have made this conclusion.

183. I also disagree with Dr. Mukherjee’s opinions that any “braid looseness” and “core popping” that the inventors experienced prevented them from making a product that would work for its intended purpose because these are really manufacturing/commercialization concerns, not proof of concept issues. “Core popping” and “braid looseness” are routine manufacturing details that are typically encountered when developing prototypes or even commercial products (Ex. 25 at 227). As Dr. Steckel testified, core popping and braid looseness are inherent in any braiding manufacturing process and quality control steps are used to eliminate any defective material when making commercial products (Ex. 25 at 227-231). “Core popping” and “braid looseness” are the type of details that are minimized when making a commercial product, so as to maximize the amount of manufactured suture that is suitable for a commercial product. My opinion is supported by the testimony of Brian Hallet of Pearsalls. As Mr. Hallet stated, core popping is a minor issue that generally arises in manufacturing braids (Ex. 23 at 192-193).

184. I also note that Dr. Mukherjee refers to a February 1990 memorandum discussing so-called “technical problems” (Mukherjee at 30). Based on all the testimony

and Dr. Steckel's notebook, I believe that he takes this memorandum out of context because it dealt with the issue of whether to pursue Dr. Steckel's concept further for certain purposes, not whether he had shown that the concept would work as a suture (Ex. 25 at 249-252). Also, I note that Dr. Mukherjee's processing "problems" discussion ignores the examples provided in the 446 patent (Ex. 2 at 7:36-63). These additional examples further show that the invention had been reduced to practice.

IX. Mr. Goodwin's Statement While Prosecuting the 446 Patent Was Not Inconsistent With Dr. Steckel's Testimony

185. I have read Mr. Witherspoon's report and, in particular, paragraphs 58-63 in which he suggests that Mr. Goodwin, one of the attorneys who prosecuted the 446 Patent, made an argument that was materially inconsistent with the testimony of Dr. Steckel. I have reviewed the arguments before the Examiner, the Burgess reference, and Dr. Steckel's testimony, and I do not agree for several reasons. First, Mr. Witherspoon misstates Mr. Goodwin's statement to the Examiner. Second, it is not clear what statements he is referring to from Dr. Steckel because he provides no citation. Third, Dr. Steckel's testimony is not inconsistent with Mr. Goodwin's statements, let alone materially inconsistent. Fourth, in any event, nothing was withheld from the Examiner because the application for the 446 patent discloses ultra high molecular weight polyethylene, UHMW PE.

186. I disagree with Mr. Witherspoon because he attributes a statement to Mr. Goodwin that he did not make. Mr. Witherspoon states that Mr. Goodwin represented to the Examiner that "if a medical designer were to actually build a suture using the braided combination of UHMW PE and polyester, then 'he would inevitably design an unacceptable suture'" (Witherspoon at ¶61). This is not what Mr. Goodwin said. Mr.

Goodwin said if a suture designer uses “*the teachings of the fishing line art* to modify a suture, then one would inevitably design an unacceptable suture” (Ex. 17 at DMI000608-609) (emphasis added). Thus, I disagree with Mr. Witherspoon because his opinion is factually incorrect; it is based on a statement that Mr. Goodwin did not make.

187. Even assuming that Mr. Witherspoon was referring to Mr. Goodwin’s statement – if a medical designer uses “the *teachings* of the fishing line art to modify a suture, then one would inevitably design an unacceptable suture” -- I still disagree with Mr. Witherspoon. Mr. Goodwin’s statement is a correct statement and there is nothing misleading about it. Burgess discusses a fishing line that is “non-stretchable” (Ex. 7 at 1). As Mr. Goodwin explained to the Examiner, those skilled in the art of developing surgical sutures would have known that it is important for a suture to have some stretchability for forming good knots. Further, as Mr. Goodwin also explained (Ex. 17 at DMI000607), Burgess does not mention knot security or knot strength or how the braid should be constructed to achieve them. Thus, if a suture designer followed Burgess’ teachings about how to make a fishing line, one would be focusing on designing an acceptable fishing line, but not an acceptable suture.

188. I also disagree with Mr. Witherspoon because he does not specifically state what it is Dr. Steckel said that was inconsistent with Mr. Goodwin’s statements (Witherspoon at ¶62). Mr. Witherspoon's report does not quote or cite to any specific testimony from Dr. Steckel. Rather, Mr. Witherspoon generally characterizes Dr. Steckel’s testimony. Since he has not specifically identified Dr. Steckel’s statement, it is difficult to address his opinions.

189. Nevertheless, even if Dr. Steckel said what Mr. Witherspoon believes he said, Dr. Steckel's testimony is not inconsistent with what Mr. Goodwin wrote to the Examiner. Mr. Goodwin's statement was directed to what a suture designer would do based on the teachings of Burgess, a fishing line reference. In contrast, Dr. Steckel's testimony was directed to his idea, not the teachings of a fishing line reference, and not how a suture designer would react based on Burgess. In fact, Dr. Steckel never testified about the substantive teachings of a fishing line reference nor the substantive teachings of Burgess, nor what would happen if a medical designer followed the teachings of a fishing line reference or Burgess. Thus, the statements are not inconsistent, let alone materially inconsistent.

190. I also disagree with Mr. Witherspoon's opinion because it appears to be based on the notion that Dr. Steckel and Mr. Goodwin did not inform the Patent Office that braiding UHMW PE and polyester would lead to an acceptable suture. But Dr. Steckel did describe his invention as including a braid of UHMW PE and PET (which is a polyester) in his patent application. Therefore, Dr. Steckel's testimony, that was allegedly not disclosed, was in-fact disclosed.

191. Not only were the statements consistent with Dr. Steckel's testimony, but they are true and, indeed, are supported by testimony of Arthrex's own witnesses. I understand that Arthrex witness, Don Grafton, testified at his deposition that knot tie down, which he defined as related to knot strength, would be poor with a UHMWPE suture (Ex. 12 at 26:14-31:1; 52-53). I also note that this is confirmed in the 234 patent application filed by Arthrex. Arthrex's 234 patent states that "[o]ne of the strongest materials currently formed into elongated strands is an ultrahigh molecular long chain

polyethylene, typically used for fishing line and the like, which is sold under the trade names Dyneema and Spectra. However, this material, while stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical application” (Ex. 14 at 1:13-21). These statements appear to be consistent with Mr. Goodwin’s statements to the Patent Office regarding the Burgess fishing line and contradict Dr. Witherspoon’s opinion that there was something misleading about Mr. Goodwin’s statements.

192. If necessary to further rebut any arguments made regarding Burgess, I may testify about the prosecution history of the 446 patent as it would be understood by a person of ordinary skill in the art. As explained above, the Examiner had rejected pending claims 21-24 as obvious over Burgess. The Examiner never stated what “braided construction” Burgess taught or that Burgess disclosed “direct intertwining contact.” In responding to this office action, Mr. Goodwin argued that it would have been non-obvious based on differences between Burgess and the claims and fishing line and suture.

193. Mr. Goodwin explained that sutures must have good knot strength and knot security. This is accurate. He also explained that for fishing line knot security and knot strength are “not as critical” because they do not “keep a stitched wound intact” (Ex. 17 at DMI000607). Again, this is accurate and supported by the fact that Burgess does not discuss either knot strength or knot security.

194. The main focus of Mr. Goodwin’s response was that since Burgess describes fishing line design criteria that are different from suture design criteria, one of ordinary skill in the art would not look to Burgess. But even if a medical designer did consider

Burgess, Burgess does not disclose any particular braid, and he would be led down a path of designing a suture to achieve the fishing line properties disclosed in Burgess, not a suture that maximizes suture properties. Burgess says nothing about how to make a braid to achieve knot security or knot strength.

195. At trial, I may use demonstrative exhibits that I have not yet created to further explain my opinions.

Dated: March 24, 2006

A handwritten signature in black ink, appearing to read "M. Hermes", written over a horizontal line.

Matthew Hermes Ph.D.

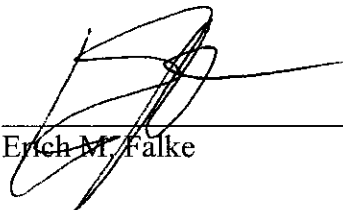
CERTIFICATE OF SERVICE

I certify that the foregoing Expert Report of Dr. Matthew Hermes was served by e-mail without exhibits and Federal Express overnight mail (Saturday delivery) with exhibits on March 24, 2006 on the following:

Charles W. Saber
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2101 L. Street, NW
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Christopher Weld, Jr.
Todd & Weld LLP
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Dated: March 24, 2006



Erich M. Falke

SALES BULLETIN

DATE 01/05/05 SUBJECT High Strength Sutures NUMBER UE133

A Biomechanical Analysis of High Strength Sutures

Recently, Stephen S. Burkhart, M.D., conducted a biomechanical analysis of new high strength sutures used primarily for arthroscopic shoulder surgery. The purpose of the study was to determine the type of braided suture that produces the optimal knot configuration maximizing both knot and loop security. The high strength sutures tested were #2 FiberWire®, #2 OrthoCord™, Herculine™, MaxBraid, UltraBraid™, and Ethibond™ (2 mm FiberTape™ was also included in this study).

Conclusions

- Tying a surgeon's knot with #2 FiberWire significantly increases knot security compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.
- Tying a surgeon's knot or sliding knot with #2 FiberWire provides the optimum balance of loop and knot security compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.
- #2 FiberWire provides the greatest loop security when tying a Weston or Roeder knot compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.
- #2 FiberWire has the greatest knot security when tying a surgeon's knot compared to #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond. Although #2 OrthoCord had the smallest loop circumference when tying a surgeon's knot the difference between the loop circumference of #2 FiberWire and #2 OrthoCord was not statistically significant.
- In straight pull-testing, #2 FiberWire had the highest ultimate strength compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.
- #2 FiberWire had the smallest percentage of elongation compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.

Methods & Materials

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Six #2 sutures were tested, FiberWire (polyethylene & polyester), Ethibond (polyester), OrthoCord (polydioxnone & polyester), Herculine (polyethylene), MaxBraid (polyethylene), and UltraBraid (polyethylene with & without a monofilament polypropylene marker). Three knots were used, the Roeder & Weston knots with three reversing half-hitches on alternating posts as well as a static surgeon's knot. Additionally, 2 mm FiberTape (polyethylene & polyester) were tied using four alternating throws. All total 133 knots were tied.

All knots were tied around a 30 mm circumference post to assure consistent loop circumference by Stephen S. Burkhart, M.D., a senior arthroscopic surgeon (Figure 1). Before testing, the knot stack was measured using calipers (Figure 2).

ARM 002188

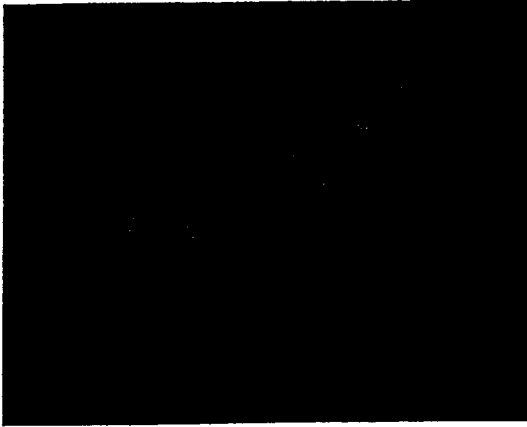


Figure 1: Knot tied over 30 mm pin.

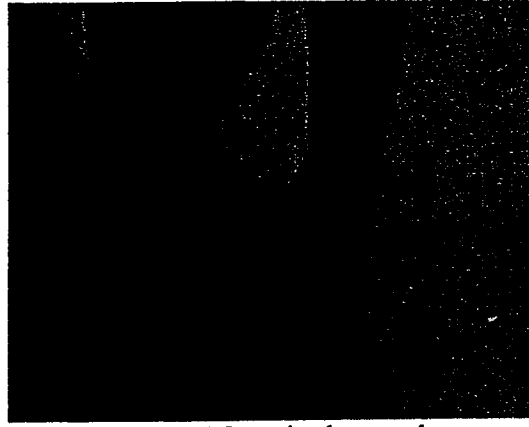


Figure 2: Measuring knot stack.

Each loop was mounted on an Instron materials testing system (model 5544, Instron, Canton, MA) to test knot and loop security. Fixtures were mounted to the base and crosshead of the Instron with two 3.95 mm diameter rods held parallel. Each loop was placed around the rods with the knots centered between the two rods (Figure 3). A 5N preload was applied at 1 mm/s and then pulled to failure at 1 mm/s. Data was collected at 500 Hz.

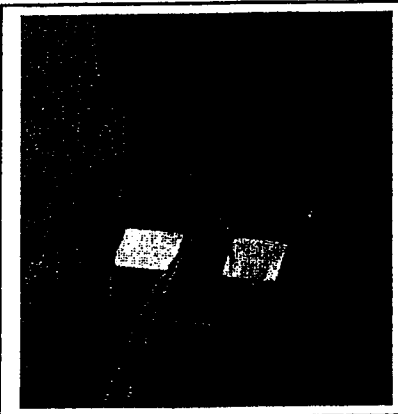


Figure 3: Instron test set up.

The loop circumference was measured at the 5N preload to assess each knot's ability to maintain a tight loop without slippage (loop security). The loop circumference was calculated based on equation 1 where C_1 = loop circumference, d = rod diameter, and x = crosshead displacement measured for the center of each rod.

$$\text{Equation 1: } C_1 = nd \times 2(x)$$

Knot security was measured as the maximum force to failure at 3 mm of crosshead displacement or suture breakage during single pull load testing (force to failure and failure mode were recorded). Three millimeters of elongation was selected as the failure mode because 3 mm or more is generally accepted in the literature. For statistical analysis one way analyses of variance (ANOVA) were used. *Post hoc* pairwise multiple comparisons were made using a Biferroni t-test. A significance level of 0.05 was used for all analyses.

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ARM 002189

Arthrex, Inc., Naples, FL
Test Report Summary and Sign-Off Sheet

Ref: RAF-04.16-1
Rev: 3
Date: 01/08/04
Approved DCN: 03310

Test Report: # TEST021104

Part number: DT PS05 T2	Rev: N/A	Description: #2 Fiberwire MED2174 Coated and Uncoated USIPG Dyed	Material: Polyethylene, Polyester
Vendor Name: Pearsalls <i>Brian Hallist</i>	Lot Numbers: N/A	Number Tested: 3/2	
Performed by: Ashley Holloway	Type of Test: Knot Tiedown	Date: 02/16/04	

Test Objective:

To determine the peak force required to advance a single half hitch using coated and uncoated Fiberwire suture.

Materials and Methods:

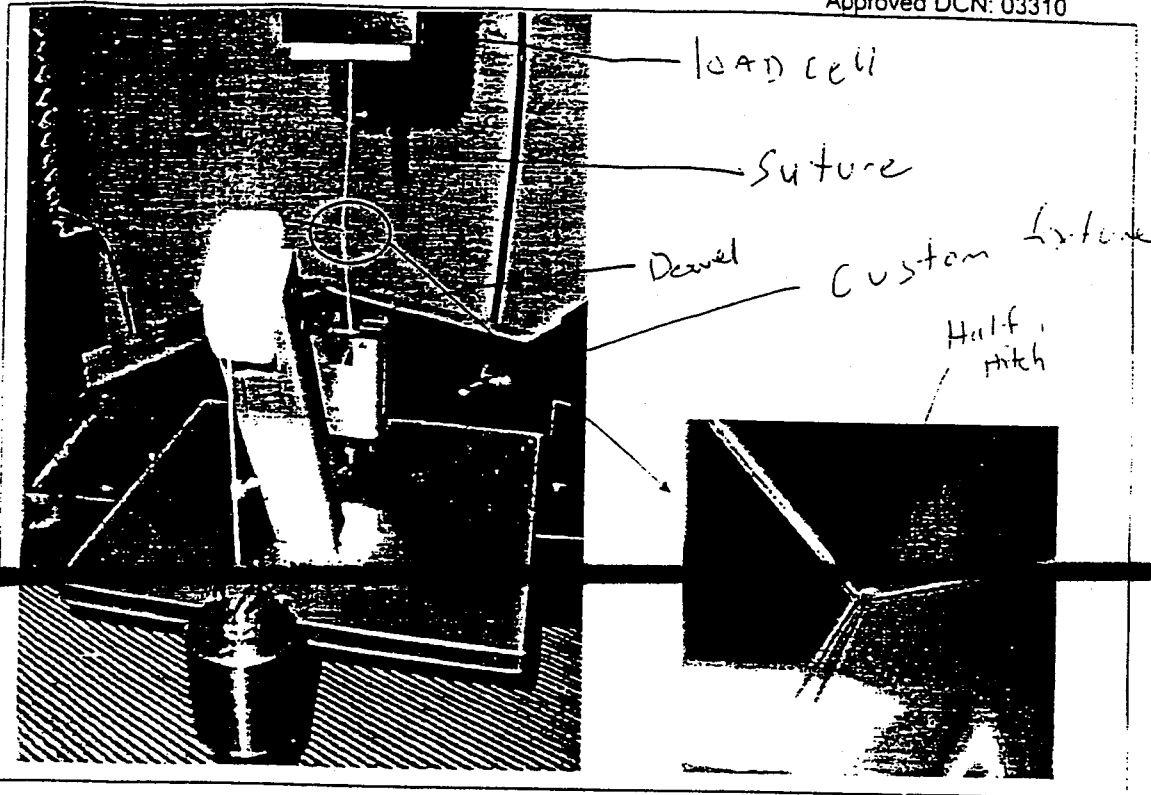
The 50lb load cell was attached to the MTS Sintech 1/S and calibrated. A custom fixture as shown was used to simulate knot tying that would occur clinically. The top end of the suture was clamped in a custom fixture that was attached to the load cell, and then a single half hitch was tied around a guide block such that the loop length was consistent between samples. A weight of .375 kg was then attached to the free end of the suture in order to tension the loop. Care was taken to tension the legs of the suture consistently. The loop was then loaded at 12 in/min for 30mm and data was collected at 200 Hz. The peak load required to cause the half hitch to slip was recorded and used for data analysis purposes.

DEPUY MITEK
EXHIBIT 343
04cv12457

Arthrex, Inc., Naples, FL
Test Report Summary and Sign-Off Sheet

Ref: RAF-04.16-1
Rev: 3
Date: 01/08/04
Approved DCN: 03310

↑ load cell movement



Data Analysis/Conclusions:

A mean peak force of 12.7 N was recorded for the coated suture. This force represents the force required to initiate slippage of the half hitch. A mean peak force of 32.9 N was recorded for the uncoated suture. A significantly greater amount of force was required to advance the uncoated suture.

2/16/04

Sample ID: coated_uncoated suture_1_021004.mss
 Method: Suture Test.msm

Test Date: 2/11/04
 Operator: Ashley Holloway

Sample Information:

Name	Value
Lot Number	n/a
Part Number	Coated/Uncoated suture test
Revision Level	#2 Fiberwire

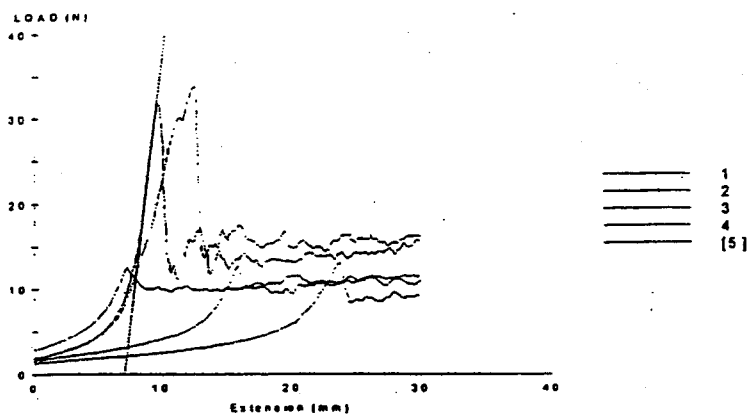
Specimen Results:

Specimen #	Peak Load Coated (N)	Specimen #	Peak Load Noncoated (N)
1	12.43	4	34.04
2	13.08	5	31.71
3	12.64		
Mean	12.72		32.88
Std. Dev.	0.33		1.65
Minimum	12.43		31.71
Maximum	13.08		34.04

Calculation Inputs:

Test Inputs:

Name	Value	Units
Break Threshold	5.620	lbf
Brk Sensitivity	95	%
Data Acq. Rate	200.0	Hz
Ext Limit HI	30.0	mm
Initial Speed	300.00	mm/min
Load Limit HI	150	N
MaxSoccmens	999	
Outer Loop Rate	100	Hz
Slack Pre-Load	5.00	N
Slowdown Extension	0.000	in
Slowdown Load	0.000	lbf
Slowdown Strain	0.000	%
Test Speed	305.00	mm/min



IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a
Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware
Corporation,

Defendant.

DEPOSITION OF: DONALD GRAFTON
DATE: March 14, 2006
TIME: 8:38 a.m. to 1:23 p.m.
LOCATION: The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112
TAKEN BY: Plaintiff
REPORTER: Deborah A. Krotz, RPR, CRR
VIDEOGRAPHER: Gene Howell, CLVS

<p style="text-align: right;">42</p> <p>1 A. What's the date on this?</p> <p>2 Q. The date on this is -- the last page is dated</p> <p>3 November 4th, 2005.</p> <p>4 A. Okay. I want to quantify this then, because</p> <p>5 you're talking about a time period after I worked for the</p> <p>6 company, so when you -- when it says in here that I'm</p> <p>7 familiar with these products, it would be at the time I</p> <p>8 had left the company. And this is -- this was written</p> <p>9 after I left the company. So I can't totally say that I</p> <p>10 am familiar with those products under that.</p> <p>11 Q. So you would agree that you were familiar with</p> <p>12 the state-of-the-art for surgical suture products as of</p> <p>13 the date you left Arthrex?</p> <p>14 A. Define state-of-the-art, sir.</p> <p>15 Q. State-of-the-art? Well, the general -- You don't</p> <p>16 have an understanding of what that means?</p> <p>17 A. I want to understand what you mean in the context</p> <p>18 of this state-of-the-art.</p> <p>19 Q. Okay.</p> <p>20 A. I mean there's -- there's -- there's --</p> <p>21 Q. This is from Pearsalls, so I can't tell you</p> <p>22 exactly what they mean, so ... Let me back up. When you</p> <p>23 were --</p> <p>24 A. I was -- I was familiar with the competitive</p> <p>25 products on the market and what we offered and how they</p>	<p style="text-align: right;">44</p> <p>1 and tensile strength; right?</p> <p>2 A. Yes.</p> <p>3 Q. Didn't that come up in your testing?</p> <p>4 A. I don't recall.</p> <p>5 Q. What was your involvement in the development of</p> <p>6 FiberWire?</p> <p>7 A. It was my idea.</p> <p>8 Q. When you say it was your idea, what do you mean</p> <p>9 by that?</p> <p>10 A. I'll give you -- Would you like the story on how</p> <p>11 FiberWire came about?</p> <p>12 Q. Sure.</p> <p>13 A. We were having issues from customers with the</p> <p>14 Tevdek suture being low tensile strength as compared to</p> <p>15 competitors' suture anchors with suture, primarily</p> <p>16 Ethicon.</p> <p>17 Q. Ethibond?</p> <p>18 A. Ethibond. This was numerous complaints from</p> <p>19 friendly surgeons, not -- not a massive amount of</p> <p>20 complaints, but it was determined that the tensile</p> <p>21 strength of the suture was not as good as the Ethicon</p> <p>22 Ethibond suture.</p> <p>23 Q. When you say friendly, do you mean friendly to</p> <p>24 Arthrex?</p> <p>25 A. Yes. And I had gotten a phone call from a Dr.</p>
<p style="text-align: right;">43</p> <p>1 compared to the competitive products.</p> <p>2 Q. Okay. And that was as of the date you left</p> <p>3 Arthrex?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And how long were you familiar with</p> <p>6 Arthrex's suture products and the competitive suture</p> <p>7 products that are in the marketplace?</p> <p>8 A. When we started marketing the product, the</p> <p>9 sutures, until the time I left.</p> <p>10 Q. Okay. So sometime when Arthrex began selling the</p> <p>11 suture from the supplier from New Mexico?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. When Arthrex shifted from the Pearsalls</p> <p>14 suture to the Tevdek suture, was there any consideration</p> <p>15 to -- or for Arthrex designing its own suture?</p> <p>16 A. No.</p> <p>17 Q. Why not?</p> <p>18 A. Because we could find a suture OEM that was</p> <p>19 available already. Why manufacture the suture when</p> <p>20 there's a readily available source?</p> <p>21 Q. Now you said you tested for the Tevdek suture</p> <p>22 before it was selected; right?</p> <p>23 A. Of course.</p> <p>24 Q. And then it came back after it was selected, the</p> <p>25 response from surgeons was that it had low knot strength</p>	<p style="text-align: right;">45</p> <p>1 Deberdino who was a surgeon at Fort Sam Houston, San</p> <p>2 Antonio. His -- his comments were that he had tied three</p> <p>3 knots the previous afternoon using the FASTak product of</p> <p>4 Arthrex -- that's a glenoid labrum device -- and had broke</p> <p>5 the knots on all three of them. And -- you know -- he</p> <p>6 said it kind of jokingly. He said, "And I didn't even</p> <p>7 work out the day before."</p> <p>8 And so he was trying to be nice about it, but</p> <p>9 bottom line was your suture sucks. Okay?</p> <p>10 And so -- you know -- we're in a position where</p> <p>11 we need to find a suture that will be competitive. I had</p> <p>12 been to Pearsalls many times working on bioabsorbable</p> <p>13 products. This was the time that you referred to earlier</p> <p>14 where I said three to five, and was familiar with suture</p> <p>15 manufacturing, the steps required to manufacture a suture.</p> <p>16 One of the trips there, Mr. Lyon had pointed out</p> <p>17 to me a -- the other products they manufactured, which was</p> <p>18 fishing line and silk used in decorated drapes. The</p> <p>19 fishing line used a ultra-high molecular weight</p> <p>20 polyethylene material that was very strong, and I -- at</p> <p>21 some point, it was decided that we would try some of that</p> <p>22 for a suture.</p> <p>23 I had Pearsalls, mainly through Brian, as being</p> <p>24 the manufacturing person --</p> <p>25 Q. Brian Hallett?</p>

12 (Pages 42 to 45)

<p>46</p> <p>1 A. That's correct -- make some Size 2 braided 2 material, send to me, and at the -- coincidentally, at the 3 same time, I had a Dr. Steve Burkhart from San Antonio and 4 a Dr. Casey Chan, who is a R & D guy in knot testing and 5 suture. They were -- they were at Arthrex at the time 6 when this material showed up. 7 We tested the material. The strength was 8 excellent. The knot slippage was very poor, would not 9 hold a knot. 10 So at that point in time, it looked like we would 11 not be able to use an alternative material of ultra-high 12 molecular weight polyethylene because the slippage of the 13 material -- because of the slippage of the material tested 14 with Casey Chan -- Dr. Chan and Dr. Burkhart. And so at 15 that point in time, the -- the product was -- was on hold. 16 I was on a trip to Chicago to the national sales 17 meeting, and I had this idea of adding PET to the 18 ultra-high molecular weight polyethylene to enhance the or 19 reduce the knot slippage of the product. I sent an e-mail 20 to Dr. Steve Burkhart and suggesting that since he was 21 familiar with the testing we had done very recently with 22 just the ultra-high molecular weight PE, of adding the 23 PET, and his -- I'll never forget the e-mail. He thought 24 that was a killer idea. 25 And so I had asked then at that time for Brian</p>	<p>48</p> <p>1 processed to make a braid. 2 Q. Okay. And how many times were you over in 3 England? 4 A. I told you already. Three to five. 5 Q. Three to five. 6 A. Approximate. 7 Q. Is that total lifetime? 8 A. That's an approximate number total lifetime, yes. 9 Q. Have you been to other manufacturing facilities 10 for sutures? 11 A. Jenzyme Tevdek. 12 Q. And how many times have you been there? 13 A. Once, I believe. 14 Q. And when you were at Jenzyme Tevdek, did you see 15 the manufacturing processes for Tevdek? 16 A. It was a dog and pony quick courtesy through the 17 facility. 18 Q. So when you came up with the idea for using 19 ultra-high molecular weight polyethylene in a suture, did 20 you -- you say you are familiar with how sutures are made? 21 A. I'm also a fisherman. There's -- you know -- 22 fishing line is -- uses ultra-high molecular weight 23 polyethylene as a material that's used for sport fishing, 24 very high strength. 25 Pearsalls made fishing line. And so they had</p>
<p>47</p> <p>1 Hallett to make me samples up of using those two materials 2 and -- and send to me. And we tested the materials, and 3 now we had a product that had superior tensile strength 4 and greater knot strength than any competitive product out 5 on the market. 6 Q. Okay. If I could just back up to a couple of 7 points that you mentioned to make sure I understand what 8 happened here. The -- You said the idea began -- or I'm 9 sorry. Back up. You said when this idea came up, you had 10 already been to Pearsalls several times? 11 A. Mmm-hmm (affirmative). 12 Q. And you were familiar with -- 13 A. Yes. 14 Q. And when this idea came up, you were familiar 15 with how sutures were manufactured? 16 A. Yes. 17 Q. Okay. And what did you mean by that? 18 A. One of the products -- projects that I worked on 19 was a bioabsorbable suture similar to what Ethicon sells 20 as Panacryl, and the difference being this was 100 percent 21 PLLA material. The -- so we worked on this for about a 22 year -- I don't know the exact time -- with many trips 23 over to Pearsalls to change the construct of the yarn to 24 enhance the tensile properties of the material. And so at 25 that time, I became familiar with how a suture is</p>	<p>49</p> <p>1 this material already available as a fishing line. So it 2 was an easy conversion -- you know -- conclusion, 3 conversion to say what if this is used as a suture 4 material, because ultra-high molecular weight polyethylene 5 is a totally inert material. 6 Q. When you saw that Pearsalls had been using 7 ultra-high molecular weight polyethylene in fishing 8 line -- 9 A. Yes. 10 Q. -- do you know how it was being used in fishing 11 line, what the construction was? 12 A. No. 13 Q. Was it a braided construction? Was it -- 14 A. I can't tell you for sure, sir. 15 Q. You don't know? 16 A. I wasn't interested in buying fishing line, so I 17 didn't look at the details of it. 18 Q. So you had -- Sitting here today, you can't tell 19 me anything at all about how the fishing line that 20 Pearsalls was making with ultra-high molecular weight 21 polyethylene was constructed? 22 A. It went through their manufacturing processes in 23 their company, but specifically how it was made, the 24 constructs, I have no idea or the size. 25 Q. In other words, you have no idea if it was all</p>

<p style="text-align: right;">50</p> <p>1 ultra-high molecular weight polyethylene or if it was 2 braided or -- 3 A. It's been too long ago. I can't tell you that. 4 Q. And your idea was to use the ultra-high molecular 5 weight polyethylene as a suture? 6 A. Yes. 7 Q. Okay. And you had Mr. Hallett make a Size 2, I 8 think you said? 9 A. Yes. 10 Q. Okay. Can you describe the construction of that 11 first -- 12 A. I don't remember now. It's been too long. 13 Q. Was it all ultra -- ultra-high molecular weight 14 polyethylene? 15 A. Initially, yes, as a test prototype material. 16 Q. Was it braided? 17 A. Yes. 18 Q. Was it an eight-carrier or a sixteen-carrier? 19 A. I don't remember. 20 Q. You said it was a Size 2 though? 21 A. Yes. 22 Q. So it was a Size 2 ultra-high molecular weight 23 polyethylene braided suture that did not have PET? 24 A. For the initial prototype material, that's 25 correct.</p>	<p style="text-align: right;">52</p> <p>1 Q. Knot security test? 2 A. Yes. 3 Q. Was that the test we drew in Exhibit Number 421? 4 A. That's correct. 5 Q. Okay. And you said the strength was excellent, I 6 believe, of the initial prototype, but the knot slippage 7 was poor; is that right? 8 A. Yes. 9 Q. Okay. When you say the slippage was poor of the 10 initial prototype, what do you mean? 11 A. Less than the tensile strength capability of the 12 existing Arthrex product. 13 Q. So the knot slippage was less than the Tevdek 14 suture? 15 A. Yes. 16 Q. And it was -- knot slippage was such that it was 17 determined that the 100 percent ultra-high molecular 18 weight polyethylene suture prototype wasn't suitable to be 19 developed? 20 A. That's correct. Yes. 21 Q. Okay. Ultra-high molecular weight polyethylene, 22 you said the knot slippage was poor? 23 A. (Witness nods head affirmatively). 24 Q. Ultra-high molecular weight polyethylene, is that 25 a lubricious material?</p>
<p style="text-align: right;">51</p> <p>1 Q. Okay. And it didn't have nylon or any other 2 material braided with it? 3 A. No. 4 Q. So the initial prototype was a ultra-high 5 molecular weight polyethylene braided suture prototype, if 6 you will? 7 A. Yes. Size 2. 8 Q. Size 2. And was the initial prototype, was it 9 coated? 10 A. I don't remember. 11 Q. Okay. Do you know if the initial prototype went 12 through any other manufacturing process like stretching or 13 heating, twisting? 14 A. I don't recall. 15 Q. Was the initial prototype 100 percent ultra-high 16 molecular weight polyethylene? 17 A. For the fourth time, yes. 18 Q. Okay. And you tested the initial prototype that 19 was 100 percent ultra-high molecular weight polyethylene 20 with Dr. Burkhardt and Dr. Chen? 21 A. Dr. Casey Chen, correct. 22 Q. Okay. And the test that you conducted with Dr. 23 Burkhardt and Dr. Chen on the ultra-high molecular weight 24 polyethylene was a knot strength test? 25 A. Knot security.</p>	<p style="text-align: right;">53</p> <p>1 A. Yes. 2 Q. And was the knot slippage of this ultra-high 3 molecular weight polyethylene poor security because of the 4 lubricity of polyethylene? 5 A. Yes. 6 Q. Yes? 7 A. Yes. 8 Q. So then you came up with the idea to braid PET 9 with the ultra-high molecular weight polyethylene to 10 reduce the knot slippage? 11 A. Yes. 12 Q. And when you say knot slippage, we're referring 13 to this knot security test? 14 A. Yes. 15 Q. So are we using the terms knot slippage and knot 16 security interchangeably here? 17 A. You are, yes. 18 Q. In your testimony? 19 A. Yes. 20 Q. So the knot security of the 100 percent 21 ultra-high molecular weight polyethylene was poor, the 22 prototype; right? 23 A. Yes. 24 Q. And your idea was to add the PET and to improve 25 the knot security?</p>

14 (Pages 50 to 53)

<p style="text-align: right;">54</p> <p>1 MR. SOFFEN: Objection; asked and answered.</p> <p>2 You've asked him the same thing multiple times. But</p> <p>3 you can answer.</p> <p>4 A. I've lost count, it's been so many times, but the</p> <p>5 answer again is yes.</p> <p>6 Q. Okay. And Dr. Burkhardt said that was a killer</p> <p>7 idea?</p> <p>8 A. What was a killer idea?</p> <p>9 Q. The killer idea was that your idea of adding</p> <p>10 PED -- PET -- I'm sorry. I'll rephrase that question.</p> <p>11 Did Dr. Burkhardt say that your idea to braid PET</p> <p>12 with the ultra-high molecular weight polyethylene to</p> <p>13 improve knot security was a killer idea?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. And then you said you had Pearsalls</p> <p>16 manufacture a prototype that had PET and ultra-high</p> <p>17 molecular weight polyethylene braided?</p> <p>18 A. Yes.</p> <p>19 Q. And you tested that prototype?</p> <p>20 A. Yes.</p> <p>21 Q. And you said that that prototype had good knot</p> <p>22 strength?</p> <p>23 A. Correct.</p> <p>24 Q. And the prototype of PET braided with ultra-high</p> <p>25 molecular weight polyethylene had good knot security?</p>	<p style="text-align: right;">56</p> <p>1 Q. I'm talking about the --</p> <p>2 A. The second prototype with the PET?</p> <p>3 Q. Correct.</p> <p>4 A. Yes.</p> <p>5 Q. The second prototype that had the coating on it?</p> <p>6 A. Yes.</p> <p>7 Q. And was that part of your initial idea, or was</p> <p>8 that -- because I thought you said your initial idea was</p> <p>9 to add the PET. Was it also to coat it, or was that</p> <p>10 something that came later?</p> <p>11 A. If you're going to market the product, it needs</p> <p>12 the coating on it, sir.</p> <p>13 Q. Okay. But the prototype that was manufactured</p> <p>14 that you asked --</p> <p>15 A. Most likely, it was coated, because it needed to</p> <p>16 be as the final product would be marketed.</p> <p>17 Q. You said most likely. Do you remember or you</p> <p>18 don't remember whether the prototype that had the PET and</p> <p>19 the ultra-high molecular weight polyethylene was coated?</p> <p>20 A. I can't tell you for sure that it was at that</p> <p>21 prototype stage.</p> <p>22 Q. Okay. Was this prototype that you had -- after</p> <p>23 you tested the prototype with PET with ultra-high --</p> <p>24 A. Excuse me. I want to change that.</p> <p>25 Q. Okay.</p>
<p style="text-align: right;">55</p> <p>1 A. Yes.</p> <p>2 Q. And the prototype of PET and ultra-high molecular</p> <p>3 weight polyethylene braided together also had good tensile</p> <p>4 strength?</p> <p>5 A. Yes.</p> <p>6 Q. And after you tested this second prototype, if</p> <p>7 you will, of the PET braided with ultra-high molecular</p> <p>8 weight polyethylene, was then the decision made to pursue</p> <p>9 trying to commercially develop this idea?</p> <p>10 A. Yes.</p> <p>11 Q. Did you -- when you made -- Who made the decision</p> <p>12 to go forward and try to commercialize this idea?</p> <p>13 A. Myself and Reinhold, surgeons that we</p> <p>14 collaborated with, marketing people. You know, it wasn't</p> <p>15 just myself.</p> <p>16 Q. Okay. Was this prototype that had the PET</p> <p>17 braided with the ultra-high molecular weight polyethylene,</p> <p>18 was it -- did it have a coating on it?</p> <p>19 A. Yes.</p> <p>20 Q. It did?</p> <p>21 A. (Witness nods head affirmatively).</p> <p>22 Q. And what was the coating?</p> <p>23 A. I forget the name. It's like a MED2174s.</p> <p>24 Q. That was on the prototype?</p> <p>25 A. Which prototype are you referring to now?</p>	<p style="text-align: right;">57</p> <p>1 A. I never got samples of constructions from</p> <p>2 Pearsalls without a coating unless I specifically asked</p> <p>3 for it not to be coated. So there's a very high</p> <p>4 probability that the suture came as -- the second</p> <p>5 prototype -- as coated.</p> <p>6 Q. That was standard for them to coat it, in other</p> <p>7 words?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. So the initial prototype that was</p> <p>10 ultra-high molecular weight polyethylene, did you ask for</p> <p>11 that not to be coated?</p> <p>12 A. No.</p> <p>13 Q. So chances are that that one was coated?</p> <p>14 A. Quite possibly.</p> <p>15 Q. After you tested the prototype of PET and</p> <p>16 ultra-high molecular weight polyethylene braided together,</p> <p>17 did you believe that it would then work as a suture?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. Is there anything else you think you</p> <p>20 needed to do in order to determine whether it would work</p> <p>21 as a suture?</p> <p>22 A. Yes.</p> <p>23 Q. What did you need to do?</p> <p>24 A. Biocompatibility toxicity testing, bioburden</p> <p>25 levels, all the design control GNP items that need to be</p>

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a
Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware
Corporation,

Defendant.

CONTINUATION
DEPOSITION OF:

PETER DREYFUSS

DATE:

December 7, 2005

TIME:

8:03 a.m. to 1:21 p.m.

LOCATION:

The Staybridge Suites
4805 Tamiami Trail North
Naples, FL

TAKEN BY:

Plaintiff

REPORTER:

Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER:

Michael Sturdevant, CLVS

<p style="text-align: right;">74</p> <p>1 Q. And if you see in the second paragraph, second 2 sentence, it says, "The Black/White Suture commonly known 3 as TigerWire has a blend of nylon and the ultra high 4 molecular weight polyethylene." Do you see that? 5 A. Yes. 6 Q. And if you skip a sentence, it says, "In place of 7 the nylon, a silk suture will be used." Do you see that? 8 A. Yes, I do. 9 Q. Is the only difference between Arthrex's 10 TigerWire and Arthrex's FiberWire with silk is the silk 11 suture is used in place of the nylon marker strand in 12 Arthrex's TigerWire product; is that right? 13 MR. SABER: Object; vague and confusing question. 14 Q. Do you understand the question? 15 A. I understand, I believe, from what I read here 16 that that is true. 17 Q. And the last time we were here, you described the 18 design and construction of the TigerWire product. Do you 19 remember that? 20 A. Yes, I understand that. 21 Q. What is the purpose of the nylon marking strand 22 in Arthrex's TigerWire product? 23 A. Identification. Visual identification. 24 Q. Is there any other purpose to the nylon marking 25 strand in Arthrex's TigerWire product?</p>	<p style="text-align: right;">76</p> <p>1 Q. But they show -- But a No. 2 TigerWire, for 2 instance, and a No. 2 FiberWire show very similar knot 3 strength, tensile strength, handleability, and what not, 4 all of the characteristics that define FiberWire? 5 A. I believe so. 6 Q. Okay. And is that true also with the 7 introduction of silk rather than a nylon marker? 8 A. I don't know. 9 Q. Do you know whether the silk used in the 10 FiberWire with silk suture affects any of the 11 characteristics of the suture? 12 A. No, I don't. 13 Q. Based on your understanding of Arthrex's 14 FiberWire with silk product, do you think you would be 15 able to draw a cross-section of the suture? 16 A. I -- No. 17 Q. No? But as far as you know, the only difference 18 between the TigerWire and a FiberWire with silk is instead 19 of the nylon, it's a piece of silk? 20 A. That would be a good generalization. 21 Q. Okay. And Don Grafton would know this 22 information? 23 A. I believe so, yes. 24 (DePuy Mitek Exhibit No. 142, Design History File 25 for FiberWire 3-0 and 4-0, ARM 6580 through 6950, was</p>
<p style="text-align: right;">75</p> <p>1 A. That's the primary purpose. I'm not sure if 2 there's secondary purposes, per se. 3 Q. Does the introduction of a nylon marking strand 4 in the TigerWire product affect any of the physical 5 characteristics of the TigerWire product? 6 A. Affect in -- 7 Q. Other than the visual distinction that you can 8 see with the introduction of a nylon marking strand, does 9 the nylon marking strand in TigerWire affect any other 10 characteristic of the braided suture? 11 A. Yes. 12 Q. What is -- what? 13 A. Minute differences in its feel and strength, 14 characteristics. 15 Q. But you would describe them as minute 16 differences? 17 A. Not enough to cause it not to become a product. 18 Q. Can you explain that? 19 A. It's -- 20 Q. In other words, the introduction of the nylon 21 marking strand doesn't affect any of the marketing 22 qualities or engineering qualities that make FiberWire 23 FiberWire; does that make sense? 24 MR. SABER: Objection; vague. 25 A. It -- They are comparable.</p>	<p style="text-align: right;">77</p> <p>1 marked for identification.) 2 Q. I'm going to hand you a document labeled DePuy 3 Mitek Exhibit 142. It's a document with Bates numbers ARM 4 6580 through 6950. 5 Have you seen Exhibit 142 before? 6 A. I believe so. 7 Q. And what is DePuy Mitek Exhibit 142? 8 A. The Design History File for FiberWire new sizes 9 -- new sizes of FiberWire. 10 Q. And what new sizes for FiberWire? 11 A. 3-0 and 4-0. 12 Q. Do you have any reason to believe the information 13 in Exhibit 142 is inaccurate? 14 MR. SABER: Objection; overbroad. 15 A. No, I don't. 16 MR. FALKE: I'm just trying to authenticate the 17 document. 18 MR. SABER: No, I have no problem with you 19 authenticating the document, but I -- you know -- this 20 is, again, a document of hundreds of pages. And to 21 ask him to -- a generalized question like that I think 22 is kind of unfair. 23 BY MR. FALKE: 24 Q. Do the instructions for use that are included 25 with all of Arthrex's FiberWire product indicate that the</p>

First Sale of Part #'s with Fiberglass				
Part #	Invoice #	Sales Order		Date
AR-7209SN	IV775366	S750821		5/24/2004
AR-7219	IV718668	S696876		2/19/2004
AR-1920BFT	IV720917	S698914		2/24/2004
AR-1920BF	IV507362	S490302		12/23/2002
AR-1925BF	IV525206	S508102		2/3/2003
AR-1920BNF	IV651950	S631500		10/23/2003
AR-1925BNF	IV665050	S644075		11/17/2003
AR-1902SF	IV567520	S549306		4/29/2003
AR-1915SF	IV499913	S482926		12/6/2002
AR-1920SF	IV630756	S610779		9/4/2003
AR-1925SF	IV617604	S597769		8/13/2003
AR-1928SF	IV578475	B560330		5/22/2003
AR-1928SNF	IV793431	B769413		6/28/2004
AR-1324BF	IV456286	S438187		8/21/2002
AR-1324BF-2	IV518381	S501012		1/20/2003
AR-1934BF	IV455709	S437535		8/20/2002
AR-1934BF-2	IV518470	S501400		1/20/2003
AR-7200	IV313535	S296191		8/9/2001
AR-7202	IV449860	S431942		8/2/2002
AR-7204	IV556046	B538607		4/4/2002
AR-7205	IV720151	S698352		2/23/2004
AR-7207	IV758811	S734791		4/26/2004
AR-7210	IV383632	S365480		2/20/2002
AR-7211	IV485324	S467769		11/1/2002
AR-7220	IV517123	S500083		1/16/2003
AR-7221	IV518488	S501431		1/20/2003
AR-7225	IV570854	S552835		5/6/2003
AR-2225S	IV616483	S596712		8/11/2003
AR-7227-01	IV781308	S756864		6/3/2004
AR-7227-02	IV780119	S755625		6/2/2004
AR-2226S	IV791766	S767483		6/23/2004
AR-7228	IV566034	S548130		4/25/2003
AR-7230-01	IV772818	S748209		5/19/2004
AR-7230-02	IV792330	S767941		6/24/2004
AR-1322BNF	IV521513	B504899		1/27/2003
AR-1322-752SF	IV518341	S518341		1/20/2003
AR-1324HF	IV662450	S662450		11/11/2003
AR-1324SF	IV459020	S440859		8/28/2002
AR-1322SXF	IV464295	S446283		9/11/2002
AR-7201	IV489157	S471372		11/12/2002
AR-7203	IV555999	S538522		4/3/2003
AR-7205T	IV710484	S689254		2/6/2004
AR-7209	IV484118	S466521		10/30/2002
AR-7209T	IV612329	S592805		7/31/2003
AR-7222	IV724540	B702613		3/1/2004
AR-7237	IV762680	S738906		4/30/2004
AR-7229-12	IV750929	S727156		4/13/2004
AR-7229-20	IV761187	B737692		4/29/2004
AR-1925BNP	IV831261	S807832		9/9/2004
AR-1920SNF	IV898169	S875373		12/30/2004
AR-1920BNP	IV831261	S807832		9/9/2004
AR-1927BF	IV918263	S897528		2/1/2005
AR-1920BT	IV848270	S825641		10/8/2004
AR-7219	IV707696	S686712		2/2/2004
AR-11796	IV731910	S709391		3/11/2004
AR-1929	IV440376	S422269		7/9/2002

"Confidential-
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Eyes Only"

ARM 3355

Deposition of:
Matthew Goodwin

January 17, 2006

Page 1

1
2 UNITED STATES DISTRICT COURT

3 DISTRICT OF MASSACHUSETTS

4 C.A. No. 04-12457 PBS

5 -----x
6 DePUY MITEK, INC.,

7 A Massachusetts Corporation,

8 Plaintiff,

9 v.

10 ARTHREX INC.,

11 A Delaware Corporation,

12 Defendants.
13 -----x

**TRAVEL
TRANSCRIPT**

14
15
16 DEPOSITION OF MATTHEW GOODWIN

17 New Brunswick, New Jersey

18 January 17, 2006

19
20 Reported by:

21 MARY F. BOWMAN, RPR, CRR

22 JOB NO.: SE 173
23
24
25

Deposition of:
Matthew Goodwin

January 17, 2006

Page 6

GOODWIN

best answer. From time to time, Lynn, your counsel, will be entering objections to my questions and unless she instructs you not to answer, then I would ask that you try to answer the question if that's OK. Do you understand?

A. Yes.

Q. If you want me to restate a question or if you have difficulty in answering a question, I will ask you to ask me to restate it. Otherwise if you don't ask me to restate it, I will assume that you understood it. Is that fair?

A. Yes.

Q. We will be taking breaks every hour or so. If you need a break in between, let me know and we will try to accommodate you at the next convenient spot. Is that OK?

A. Yes.

Q. Is there any reason you can think of today, are there any distractions in your life or anything going on that would prevent you from giving your best testimony today, your most honest testimony today?

A. No.

Q. Can you please walk me through your

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GOODWIN

A. I had two other positions.

Q. Can you walk me through those?

A. Yes, I worked for the Dow Chemical Company in Midland, Michigan for two and a half years. Subsequent to that, I worked for Exxon Chemical Company for about eight months before coming to Johnson & Johnson in 1989.

Q. What was your position in 1989?

A. Patent attorney.

Q. And today you are associate patent counsel?

A. Yes.

Q. Did you have any attorneys working under you in 1989?

A. No, I did not.

Q. How many do you have working under you today?

A. Four.

Q. Who is your supervisor, who is your direct boss?

A. Joseph Shirtz.

Q. How do you spell his last name?

A. S-H-I-R-T-Z.

Q. And what is his title?

Page 7

GOODWIN

education from high school, past high school.

A. I graduated from the University of Maryland with a bachelor's degree in chemical engineering. I graduated from the Temple University School of Law in 1986.

Q. Any other formal education?

A. No.

Q. And you are currently employed?

A. Yes.

Q. By whom?

A. Johnson & Johnson.

Q. Where is that?

A. In New Brunswick, New Jersey.

Q. What is your job there at Johnson & Johnson?

A. I am currently associate patent counsel, I am a patent attorney working in the law department. I have a group of patent attorneys that work for me and we support certain of the medical device companies of Johnson & Johnson.

Q. Did you have a job between law school and your job at Johnson & Johnson?

A. Yes.

Q. How many?

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GOODWIN

A. Associate patent counsel.

Q. Same title but he is your supervisor?

A. Yes.

Q. Is there a patent counsel?

A. Phil Johnson is the chief patent counsel.

Q. Did you review any materials for this deposition today?

A. Yes.

Q. And what was that?

MS. MALINOSKI: And I will instruct you not to answer based on work product. If he identifies a specific document that's OK. Otherwise, you are not entitled to that particular information.

Q. Did you review any deposition transcripts for today's deposition?

A. No.

Q. You didn't review Mr. Woodrow's deposition transcript?

A. No.

Q. You didn't review Mr. Jamialkowski's deposition transcript?

A. No.

3 (Pages 6 to 9)

Deposition of:
Hal Brent Woodrow

November 2, 2005

Page 1

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS
C.A. No. 04-12457 PBS

**READ & SIGN
COPY**

-----x
DePUY MITEK, INC.,
a Massachusetts corporation,
Plaintiffs,
v.
ARTHREX, INC.
a Delaware Corporation,
Defendant.

-----x
DEPOSITION OF HAL BRENT WOODROW
New Brunswick, New Jersey
November 2, 2005

Reported by:
MARY F. BOWMAN, RPR, CRR
JOB NO. 97

Deposition of:
Hal Brent Woodrow

November 2, 2005

Page 6

WOODROW

A. Yes, I went to high school -- well, skip high school, start with college. Went to the University of Oklahoma in 1976, graduated with a degree in 1980 in political science, 1981 in botany, proceeded on to the University of Oklahoma Law School in 1981, graduated in 1984 with a JD. Let's see, went to work for a law firm for a bit. Then went back to school to pick up some additional training in chemical engineering.

Q. Was that a degree, in chemical --

A. It was for a master's degree but I didn't complete the degree. I was hired by Phillips Petroleum in 1987 as a patent attorney.

Q. And you have been a patent attorney since 1987?

A. Yes.

Q. Are you registered with the patent office?

A. Yes, I am registered with the patent office. At Phillips Petroleum I worked doing biotechnology, polymers and fibers. I worked with their Phillips Fibers Division. I was with them from 1987 until 1991 when I began working with

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WOODROW

MR. TAMBURRO: I am going to ask the court reporter to mark Plaintiff's Exhibit 1 and ask you to take a look at that.

(Exhibit 1, notice of deposition marked for identification, as of this date.)

Q. Have you seen this document, Mr. Woodrow?

A. I am checking. I have seen parts of this document.

Q. Can I ask you to turn to topic 17, which is -- there is no page number, but topic 17. Do you see that?

A. Yes.

Q. Can you take a moment to review topic 17 and let me know if you are prepared to testify today on that subject matter?

A. Yes. I am prepared to testify on this subject matter.

Q. What did you do to prepare to testify on that subject?

A. I reviewed a document and discussed -- MS. MALINOSKI: I will caution you to the extent that you would reveal any privileged communications, not to reveal the

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WOODROW

Johnson & Johnson, began working for Johnson & Johnson, and I have been with Johnson & Johnson since 1991.

My first assignment at Johnson & Johnson was with McNeil Consumer which makes Tylenol and similar products and then shortly thereafter, I started working with Ethicon products or Ethicon and worked with them from 1992 until I believe it was 1999, working primarily with sutures and related inventions.

Q. Since '99, where have you been?

A. Since '99, I have been with Johnson & Johnson working in the pharmaceutical group.

Q. Is that here in New Brunswick?

A. Yes.

There is one other thing. While I was at Johnson & Johnson, you asked about educational experience. In the last couple of years, I have completed a Masters in microbiology and molecular genetics.

Q. Microbiology and molecular --

A. Genetics.

Q. Intense subject matter.

A. Yes.

Page 9

WOODROW

substance of any privileged communication.

A. Let me rephrase the question -- rephrase the answer. I have reviewed a document and knowledge related to Ethicon's licenses related to sutures.

Q. Maybe I misunderstood. You reviewed a document and knowledge related to -- I thought that's what you said?

A. Yes.

Q. Did you speak with anybody at Ethicon to prepare for this topic?

A. I spoke with one of the attorneys at Ethicon.

Q. Who was that?

A. Matt Goodwin.

Q. Matt Goodwin?

A. Um-hm.

Q. Who was he?

A. He is one of the patent attorneys that works at Ethicon.

Q. Is he your supervisor?

A. No.

Q. How many patent attorneys are at Ethicon today?

3 (Pages 6 to 9)

Deposition of:
Hal Brent Woodrow

November 2, 2005

Page 154

WOODROW

statements made regarding what Kaplan does not teach?

A. Yes.

Q. Did Ethicon still believe that Kaplan did not teach or suggest how its sheath yarn component is to be fabricated from the dissimilar individual filaments and that Kaplan didn't provide any guidance as to how the dissimilar individual filaments are to be braided?

MS. MALINOSKI: I think that's asked and answered.

Q. Let me restate that. At the time the amendment was made, August 3, 1993, did Ethicon still believe that Kaplan was a deficient reference and decided to amend anyway?

MS. MALINOSKI: Objection. And again, same objection based on privileged and work product.

Again, if you don't think you could answer that based on privilege or work product, then I will instruct you not to answer.

A. I believe you are asking for a statement of mental state at the time I signed the amendment which I believe would be privileged work

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WOODROW

A. The amendment states the claims have been amended -- the amendment claims claim 21 has been replaced to has been re-- the amendment states that claim 21 has been amended to place this claim in proper form for allowance further. In discussing Kaplan, it says --

Q. Where are you reading from, sir?

A. DMI 259.

Q. Where?

A. About third paragraph, "Further it states applicant submits that claim 21 has been and is not anticipated by Kaplan and amended."

Q. So the intent to was to amend to overcome the rejection based on Kaplan?

MS. MALINOSKI: Objection, mischaracterizes his testimony.

A. There are two rejections in front of -- that this amendment deals with and the first one talks, the first paragraph I read talks about Kaplan. And the second reference, the second argument I think says -- it says, "However applicants submit that claims 21 through 4 are patentable over these documents" -- right, those would be the amended claims.

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WOODROW

product.

Q. OK. So you are not going to answer on those grounds?

A. Yes.

Q. Do you know why Ethicon put you in charge of this case and removed Mr. Goodwin?

A. Mr. Goodwin took another assignment in Cincinnati.

Q. Mr. Goodwin is no longer with Ethicon?

A. Mr. Goodwin went to Cincinnati to work with Ethicon Endo and then returned later to work again with Ethicon.

Q. So he moved, changed jobs basically, that's why he was removed from the application, from prosecuting the application?

A. That's why he ceased prosecuting. I don't know whether removed -- he went on to another job.

Q. Was this claim 21 amended to overcome the rejection based on Kaplan?

MS. MALINOSKI: To the extent that calls for privileged or work product information, I instruct you not to answer. But otherwise, you can.

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WOODROW

Q. Was Ethicon's understanding at the time it drafted this response, this amendment, that Kaplan did not disclose a sheath yarn that contained only nonbioabsorbable material?

MS. MALINOSKI: Objection, vague.

Q. Let me ask a better question.

What was Ethicon's belief as to what Kaplan taught regarding the materials on the sheath of Kaplan?

A. That the sheath yarn is a biocompatible -- the sheath yarn is biocompatible and it is bioabsorbable or semibioabsorbable.

Q. Where are you reading from?

A. See below, DMI 259, paragraph -- third paragraph.

Q. The next sentence says, "Claim 21 as amended does not claim a sheath yarn composed of a bioabsorbable yarn." Do you see that?


A. Yes.

Q. Does that imply that Kaplan does have a bioabsorbable yarn in its sheath?

A. Yes. It is -- what is said above. The sheath yarn being biocompatible -- biocompatible yarn that is bioabsorbable or

40 (Pages 154 to 157)

1W 1270368



THE UNITED STATES OF AMERICA


TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

February 04, 2005

THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE
RECORDS OF THIS OFFICE OF THE FILE WRAPPER AND CONTENTS
OF:

APPLICATION NUMBER: 07/838,511
FILING DATE: February 19, 1992
PATENT NUMBER: 5,314,446
ISSUE DATE: May 24, 1994



By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

N. Woodson
N. WOODSON
Certifying Officer

PART () OF PART(S)

7 838511		PATENT DATE MAY 24 1992		PATENT NUMBER 5314446	
SERIAL NUMBER 07/838,511	FILING DATE 02/19/92	CLASS 606	SUBCLASS	GROUP PART I 1504	5314446

ALASTAIR W. HUNTER, BRIDGEWATER, NJ; ARTHUR TAYLOR JR., PLAINFIELD, NJ;
MARK STECKEL, MAINEVILLE, OH.

CONTINUING DATA***
VERIFIED

FOREIGN/PCT APPLICATIONS***
VERIFIED

FOREIGN FILING LICENSE GRANTED 03/05/92

Foreign priority claimed USC 119 conditions met	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> no	AS FILED	STATE OR COUNTRY NJ	SHEETS DRWGS. 3	TOTAL CLAIMS 24	INDEP. CLAIMS 1	FILING FEE RECEIVED \$770.00	ATTORNEY'S DOCKET NO. ETH-782
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ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

STERILIZED HETEROGENEOUS BRAIDS

U.S. DEPT. of COMM.-Pat. & TM Office—PTO-436L (rev. 10-78)

PTS OF APPLICATION
ED SEPARATELY

DATE OF ALLOWANCE MAILED 11-18-93		PREPARED FOR ISSUE CHRIS RAYMOND Assistant Examiner		CLAIMS ALLOWED Total Claims 12	
ISSUE FEE Int. Due 70.00		Date Paid 2-18-94		DRAWING Sheets 3	
Label Area		GEORGE F. LESMIES SUPERVISORY PATENT EXAMINER GROUP 150 Primary Examiner		ISSUE BATCH NUMBER 567	
Class 606		Subclass 231		WARNING: The information disclosed herein may be restricted. Unauthorized disclosure prohibited by the United States Code Title 35, Sections 122, 181 and 368. Possession outside the U.S. Patent & Trademark Office is restricted to authorized and contractors only.	

PTO-436
10/99

BAR CODE LABEL



U.S. PATENT APPLICATION

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT
07/838,511	02/19/92	264	1304

APPLICANT

ALASTAIR W. HUNTER, BRIDGEWATER, NJ; DENNIS D. JAMOLKOWSKI, LONG VALLEY, NJ; ARTHUR TAYLOR JR., PLAINFIELD, NJ; MARK STECKEL, MAINEVILLE, OH.

CONTINUING DATA***
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FOREIGN/PCT APPLICATIONS***
VERIFIED

FOREIGN FILING LICENSE GRANTED 03/05/92

STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS	FILING FEE RECEIVED	ATTORNEY DOCKET NO.
NJ	3	24	1	\$ 770.00	ETH-782

ADDRESS

ROBERT L. MINIER
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TITLE

STERILIZED HETEROGENEOUS BRAIDS

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By authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

Date

Certifying Officer

87 838511

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

DF11186 02/28/92 07838511 10-0750 110 101 770.00CH ETH-782

PTO-1556
(5/87)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000013



Case Docket No.: ETH-782

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is the patent application of

Inventor: Alastair Hunter et al.

For : STERILIZED HETEROGENEOUS BRAIDS

Enclosed are:

- ☒ Three (3) sheets of drawings (Formal).
- ☒ Two signed Declarations and Powers of Attorney.
- ☒ Two assignments of the invention to Ethicon, Inc.
- ☐ A certified copy of a _____ application.
- ☐ Associate Power of Attorney.
- ☒ Information Disclosure Statement.
- ☒ One stamped, self-addressed postcard for the PTO Mail Room date stamp.

CLAIMS AS FILED

(1)	(2)	(3)	(4)	(5)
FOR:	NUMBER FILED	NUMBER EXTRA	RATE	BASIC FEE \$690.00
TOTAL CLAIMS	24 - 20 =	4	x 20.00	\$ 80.00
INDEPENDENT CLAIMS	1 - 3 =	0	x 72.00	\$ 000.00
MULTIPLE DEPENDENT CLAIMS	no		\$220.00	\$ 000.00

TOTAL FILING FEE \$ 770.00

<input checked="" type="checkbox"/>	FEE FOR RECORDING ASSIGNMENT	\$40.00	\$ 40.00
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TOTAL FEES \$ 810.00

- ☒ Please charge Deposit Account No. 10-750/ETH-782/MSG in the amount of \$810.00. Three copies of this sheet are enclosed.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required in connection with the filing of this communication, or credit any overpayment, to Account No. 10-750/ETH-782/MSG. Three copies of this sheet are enclosed.
- ☐ A check in the amount of \$_____ to cover the total fee is enclosed.
- ☒ Address all correspondence to Robert L. Minier, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933-7003.

Matthew S. Goodwin
Attorney of Record
Reg. No. 32,839

Matthew S. Goodwin
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2791
February 19, 1992

VIA EXPRESS MAIL NO. HB346860113
MAILED FEBRUARY 19, 1992

DePuy Mitek, Inc. v. Arthrex, Inc.

C.A. No.04-12457 PBS

DMI000014



DOCKET NO. ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Alastair Hunter et al.
For : STERILIZED HETEROGENEOUS BRAIDS

Express Mail Certificate

"Express Mail" mailing number HB346860118

Date of Deposit February 19, 1992

I hereby certify that this complete application, including specification pages, claims, formal drawings, Information Disclosure Statement, PTO-Form 1449, Assignments, and Declarations and Powers of Attorney, is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patent and Trademarks, Washington, D.C. 20231.

Matthew S. Goodwin

(Typed or printed name of person mailing paper or fee)

Matthew S. Goodwin

(Signature of person mailing paper or fee)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000015



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- 1 -

TITLE OF THE INVENTION

STERILIZED HETEROGENEOUS BRAIDS

5 BACKGROUND OF THE INVENTION

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5 U.S. Patent 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutylate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Patent 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ -caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

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20 An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Patent 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

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25 More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Patent 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite

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sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by Figure 3 which is described in detail below),
5 apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application
10 discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be
15 coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve
20 braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently
3 relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure
25 which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be
30 relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

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In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare
5 braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

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SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a
15 sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of
20 filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a
25 combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the
30 heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying

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the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved
5 pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are
10 useful as surgical sutures or ligatures, as well as for the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

DECL 15 BRIEF DESCRIPTION OF THE DRAWINGS

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Figure 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

20 Figure 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

25 Figure 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

30 DECL F DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at

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least two sets of dissimilar yarns mechanically blended by
intertwining the dissimilar yarns in a braided
construction. The yarns are continuous and discrete, so
therefore each yarn extends substantially along the entire
5 length of the braid and maintains its individual integrity
during braid preparation, processing and use.

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10 The heterogeneous braids of this invention can be
conventionally braided in a tubular sheath around a core
of longitudinally extending yarns, although such a core
may be excluded, if desired. Braided sheath sutures with
central cores are shown in U.S. Patent Nos. 3,187,752;
4,043,344; and 4,047,533, for example. A core may be
advantageous because it can provide resistance to
15 flattening, as well as increased strength. Alternatively,
the braids of this invention can be woven in a spiral or
spiroid braid, or a lattice braid, as described in U.S.
Patent Nos. 4,959,069 and 5,059,213.

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20 The dissimilar yarns of the first and second set of yarns
are braided in such a manner that at least one yarn from
the first set is directly intertwined with, or entangled
about, a yarn from the second set. Direct mechanical
blending of individual, dissimilar yarns therefore occurs
25 from the interweaving and interlocking of these dissimilar
yarns, enhancing yarn compatibility and the overall
physical and biological properties of the heterogeneous
braid. Preferably, every yarn from the first set is in
direct intertwining contact with a yarn of the second set
30 to achieve the maximum degree of mechanical blending of
the dissimilar yarns.

The first and second fiber-forming materials which make up
the filaments of the first and second set of yarns,

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respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

5 The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance
10 dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some
15 hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ϵ -caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids
20 exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

25 Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve
30 the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle

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of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluoroethylene copolymers (PETFE), the polychlorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

15

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

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In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below

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about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

10

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of Figure 1 for the preparation of a braided multifilament.

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The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and 24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

25

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of Figure 1 are dispensed upward

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with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

40 5 In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid.

40 10 In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

15 40 Advantageously, as illustrated in Figure 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

20 Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

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Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing

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stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Patent 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tying a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tying knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is

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determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

5

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

10

CL

EXAMPLES

15

P

B

20

B^F

25

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Patent 4,470,941.

CONTROL I

CL

PB33

30

P

FIBER MATERIALS: An 8x0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each

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B
B
B
5
CL
PB 33
P
B 15
CL
20
PB 33
B 25
P
30
B
B

carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225 C°.

CONTROL II

FIBER MATERIALS: An 8x0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8x0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm.

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The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300 C° and for a longer residence time to facilitate melting of the PET fibers.

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The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gmXcm ²)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.87			0.0966	

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c = (Vf_a) (P_a) + (Vf_b) (P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in Figure 2, which shows a plot of tensile strength versus

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volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

5 Surprisingly, the bending rigidity of the heterogeneous
braids in EXAMPLES I and II do not follow the rule of
mixtures, and show an enhanced bending rigidity relative
to the weighted average of its components. This is shown
in Figure 3 as a plot of bending rigidity versus %PTFE in
10 the braids. Bending rigidity is the inverse of
pliability, and is obtained by measuring the slope of the
bending moment-radius of curvature plot of a suture strand
in pure bending. Hence lower bending rigidity relates to
a more pliable suture, which is a highly desirable
15 property. The mechanism of this enhanced pliability is
believed to be internal lubrication of the braid by the
"solid lubricant" behavior of the low surface energy PTFE.

FB
20 U.S. Patent 4,470,941 discloses the preparation of a
"composite" suture with a monofilament-like surface made
from multifilament yarns. The composite suture is
composed of two different synthetic polymer fibers, which
is thermally processed to melt one of the fibers to form
a continuous matrix. This process was utilized to produce
25 the PRIOR ART I example, the data of which is shown in
Table 1 and Figure 3. It is observed that the melting of
the PET fibers significantly increases the braid bending
rigidity due to the bonding of the "non-melted" fibers
together, hence resulting in a less pliable braid of
30 diminished utility.

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WHAT IS CLAIMED IS:

1. A heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and:
- a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and
- b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.
2. The heterogeneous braid of claim 1 wherein the first and second fiber-forming materials are nonmetallic.
3. The heterogeneous braid of claim 2 wherein the first and second fiber-forming materials are synthetic fiber-forming polymers.
4. The heterogeneous braid of claim 3 wherein the synthetic fiber-forming polymers are bioabsorbable.
5. The heterogeneous braid of claim 4 wherein the bioabsorbable polymers are derived from a monomer selected from the group consisting of glycolic acid, glycolide, lactide, p-dioxanone, ε-caprolactone, trimethylene carbonate, and mixtures thereof.
6. The heterogeneous braid of claim 3 wherein the fiber-forming polymers are nonabsorbable.

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3 ^{Surgical suture}
 7. The ~~heterogeneous braid~~ of claim ¹~~6~~ wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

5 4 ^{Surgical suture}
 8. The ~~heterogeneous braid~~ of claim ³~~7~~ wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

9. The heterogeneous braid of claim 8 wherein the first set of yarns is ~~PTFE, FEP, PFA, PVDF, PETFE, PP or PE.~~

5 ^{Surgical suture}
 10. The ~~heterogeneous braid~~ of claim ⁴~~9~~ wherein the first set of yarns is PTFE.

15 6 ^{Surgical suture}
 11. The ~~heterogeneous braid~~ of claim ⁵~~10~~ wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

20 7 ^{Surgical suture}
 12. The ~~heterogeneous braid~~ of claim ⁶~~11~~ wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

25 13. The heterogeneous braid of claim 12 wherein the second set of yarns is ~~PET, nylon or aramid.~~

8 ^{Surgical suture}
 14. The ~~heterogeneous braid~~ of claim ¹~~13~~ wherein the second set of yarns is PET.

30 15. The heterogeneous braid of claim 14 wherein each yarn from the first set is in direct intertwining contact with a yarn from the second set.

16. The heterogeneous braid of claim 15 wherein the braid encloses a core of longitudinally extending yarns.

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17. The heterogeneous braid of claim 16 wherein the longitudinally extending yarns are PET.

9 surgical suture 8
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5 18. The heterogeneous braid of claim 17 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10 surgical suture 9
10 19. The heterogeneous braid of claim 18 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11 surgical suture 1
20. The heterogeneous braid of claim 19 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

21. A surgical suture comprising the heterogeneous braid of claim 1.

22. A surgical suture comprising the heterogeneous braid of claim 19.

23. The surgical suture of claim 21 wherein the suture is attached to a needle.

12 8
24. The surgical suture of claim 22 wherein the suture is attached to a needle.

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ABSTRACT

SA

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Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

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Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

EA

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DOCKET NO. ~~EPH-781~~

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DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

STERILIZED HETEROGENEOUS BRAIDS,

the specification of which

(check one) [X] is attached hereto.

[] was filed on as

Application Serial No.

and was amended on
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed: NONE

VIA EXPRESS MAIL NO. HB346860118
MAILED FEBRUARY 19, 1992

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI000037

- 2 -

Prior Foreign Application(s):

Country	Application Number	Date of Filing	Priority Claimed Under 35 U.S.C. 119
		Day/Mo./Year	<input type="checkbox"/> YES <input type="checkbox"/> NO
		Day/Mo./Year	<input type="checkbox"/> YES <input type="checkbox"/> NO
		Day/Mo./Year	<input type="checkbox"/> YES <input type="checkbox"/> NO

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.

Filing Date

Status (patented,
pending, abandoned)

Application Serial No.

Filing Date

Status (patented,
pending, abandoned)

5 I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith as well as to file equivalent patent applications in countries foreign to the United States including the filing of international patent applications in accordance with the Patent Cooperation Treaty: Robert L. Minier (Reg. #20,083), Audley A. Ciamporzero, Jr. (Reg. #26,051), Steven P. Berman (Reg. #24,772), Jason Lipow (Reg. #25,509), and Matthew S. Goodwin (Reg. #32,839), One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

Address all telephone calls to Matthew S. Goodwin at telephone no. (908) 524-2791.

- 3 -

Address all correspondence to, Robert L. Minier, One Johnson & Johnson Plaza, New Brunswick, NJ 08933-7003.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1 Inventor's Signature:
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or First Inventor

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Dennis D. Jamiolkowski

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Residence: 20 Fawnridge Drive, Long Valley, New Jersey 07853 NJ
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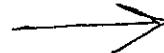
3 Inventor's Signature:
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Inventor, If Any

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Arthur Taylor, Jr.

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TO:
lev. 100

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000040

[REDACTED]

As a below named inventor, I hereby declare that:

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

STERILIZED HETEROGENEOUS BRAIDS,

the specification of which

[illegible]

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed: NONE

VIA EXPRESS MAIL NO. HB346860118
MAILED FEBRUARY 19, 1992

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000041

- 2 -

Prior Foreign Application(s):

Country	Application Number	Date of Filing	Priority Claimed Under 35 U.S.C. 119
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		Day/Mo./Year	<input type="checkbox"/> YES <input type="checkbox"/> NO
		Day/Mo./Year	<input type="checkbox"/> YES <input type="checkbox"/> NO

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status (patented, pending, abandoned)
------------------------	-------------	---------------------------------------

Application Serial No.	Filing Date	Status (patented, pending, abandoned)
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I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith as well as to file equivalent patent applications in countries foreign to the United States including the filing of international patent applications in accordance with the Patent Cooperation Treaty: Robert L. Minier (Reg. #20,083), Audley A. Ciamporcero, Jr. (Reg. #26,051), Steven P. Berman (Reg. #24,772), Jason Lipow (Reg. #25,509), and Matthew S. Goodwin (Reg. #32,839), One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

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- 3 -

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or First Inventor


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Date: _____

Citizenship:
Residence:
Post Office Address:

Inventor's Signature:
Full Name of Third Joint
Inventor, If Any

Date: _____

Citizenship:
Residence:
Post Office Address:

(Supply similar information and signature for fourth and subsequent joint inventors.)

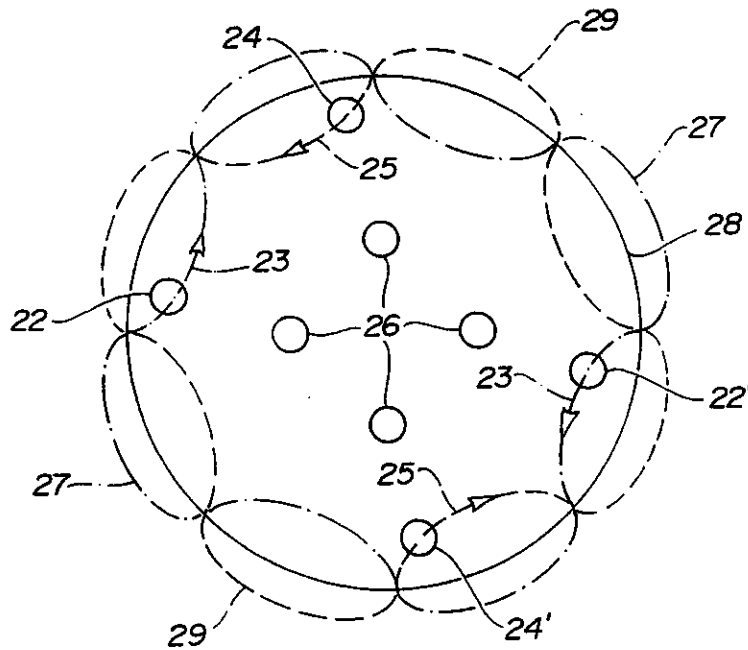


DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
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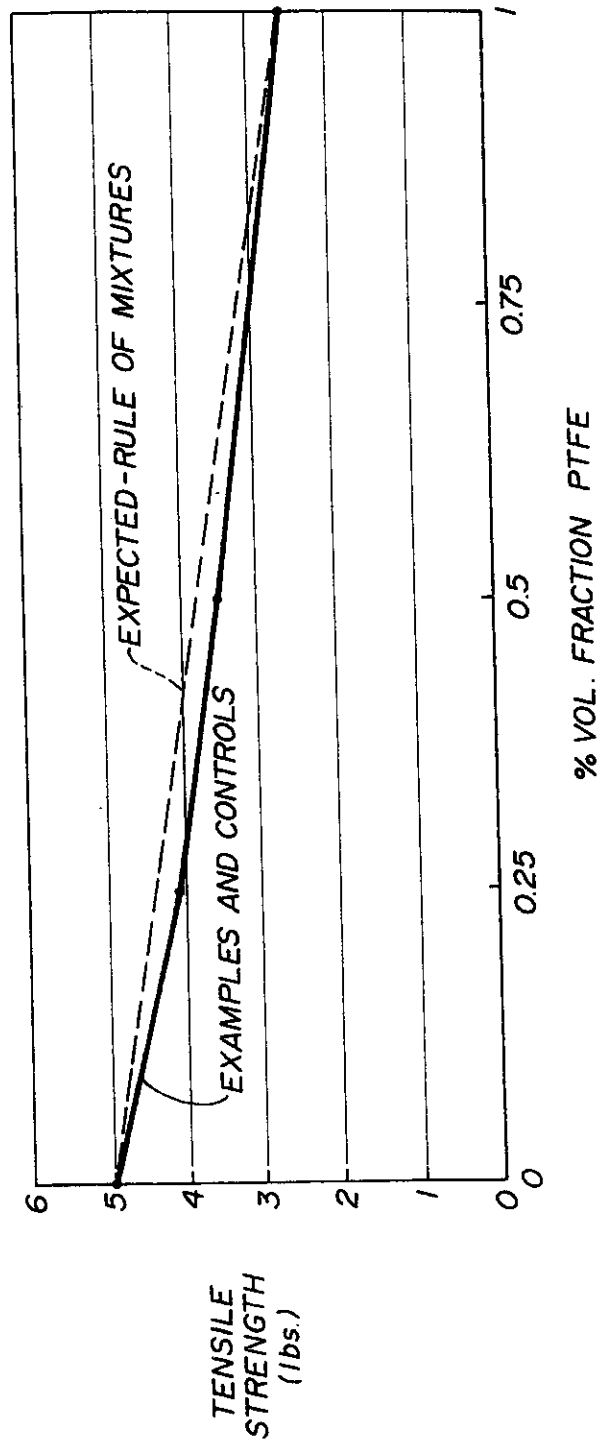
FIG-1

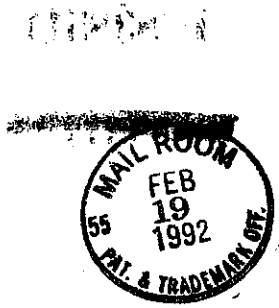




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FIG-2





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FIG-3

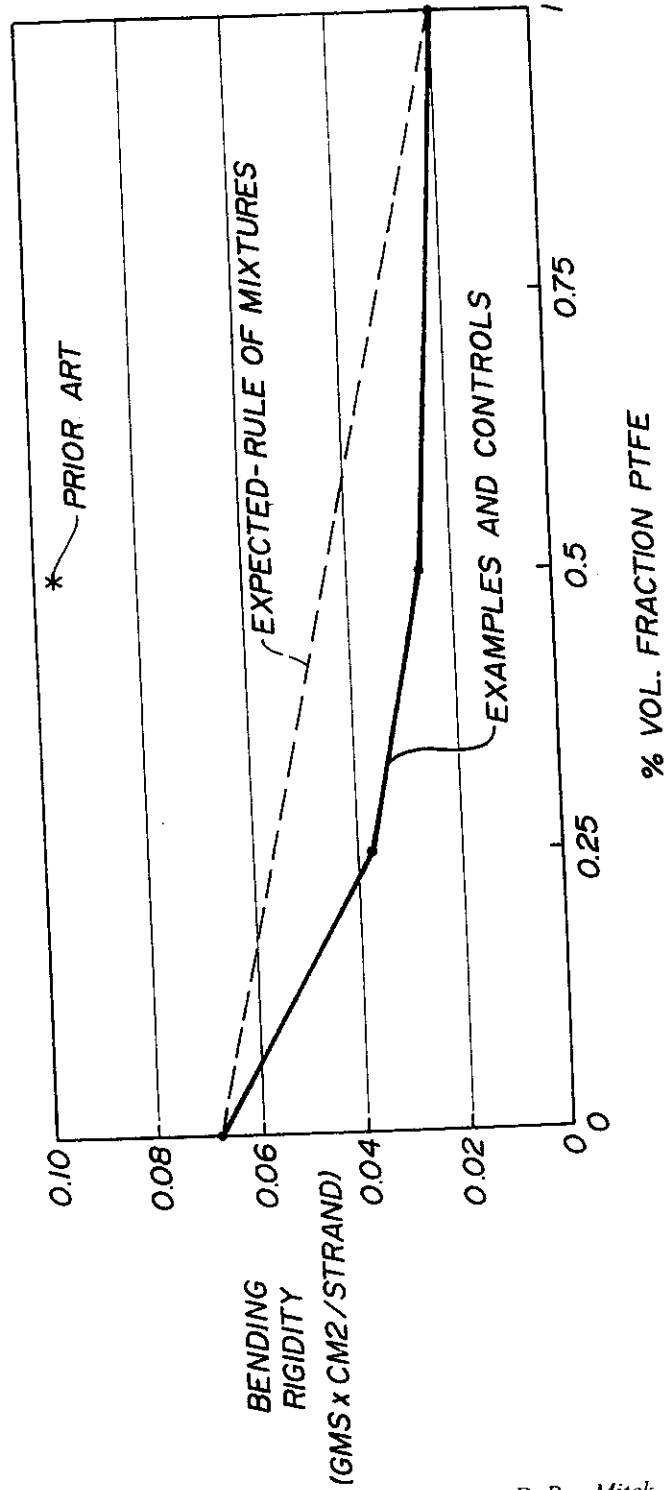
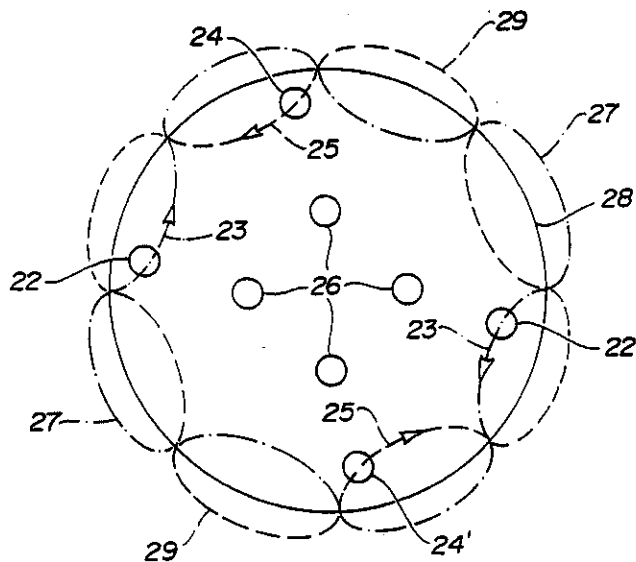


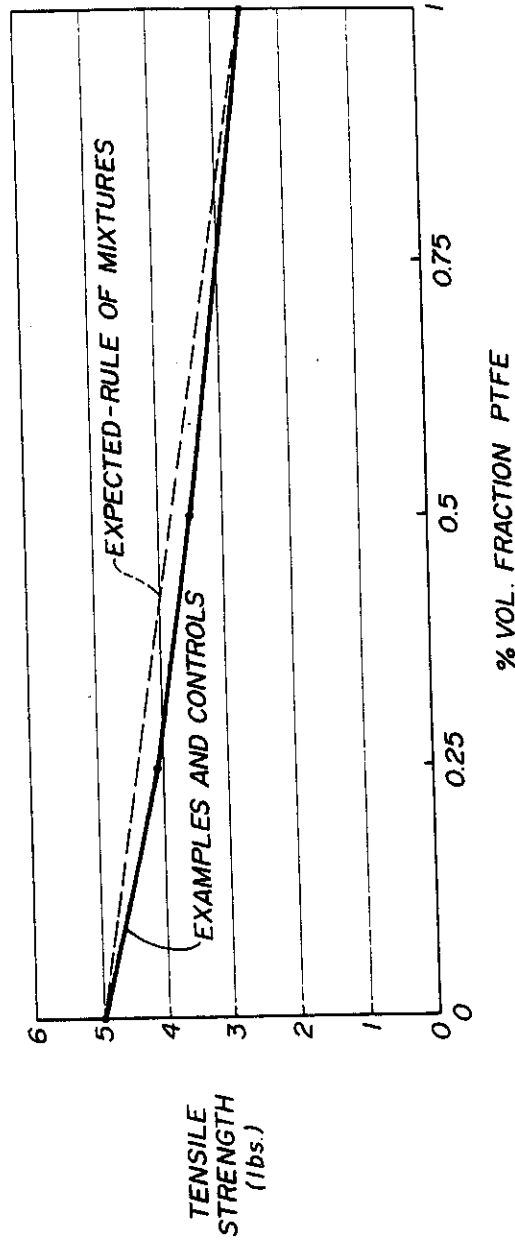


FIG-1



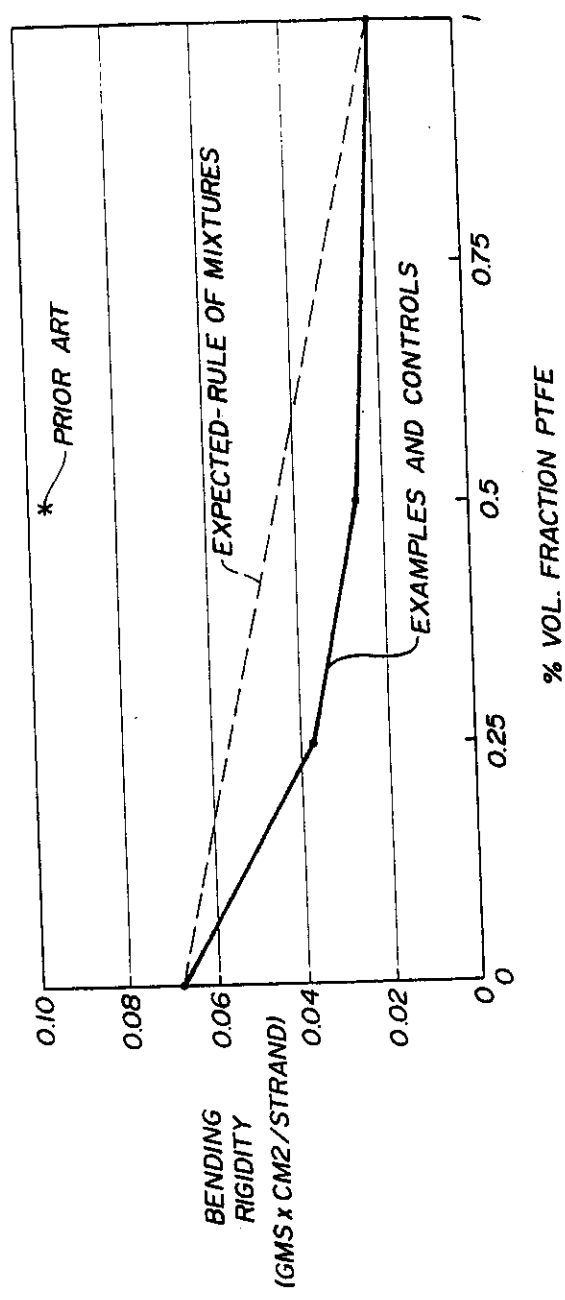
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FIG-2



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FIG-3



US005314446A

United States Patent [19][11] **Patent Number:** 5,314,446

Hunter et al.

[45] **Date of Patent:** May 24, 1994[54] **STERILIZED HETEROGENEOUS BRAIDS**[75] **Inventors:** Alastair W. Hunter, Bridgewater;
Arthur Taylor, Jr., Plainfield, both of
N.J.; Mark Steckel, Maineville, Ohio[73] **Assignee:** Ethicon, Inc., Somerville, N.J.[21] **Appl. No.:** 838,511[22] **Filed:** Feb. 19, 1992[51] **Int. Cl.⁵** D04C 1/00[52] **U.S. Cl.** 606/231; 606/228;
87/7; 87/9; 428/370[58] **Field of Search** 606/228, 230, 231;
87/7, 8, 9; 428/225[56] **References Cited****U.S. PATENT DOCUMENTS**

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3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
4,047,533	8/1977	Perciaccante et al.	128/335.5
4,052,988	10/1977	Doddi et al.	128/335.5
4,141,087	2/1979	Shalaby et al.	3/1
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WO86/00020	1/1986	PCT Int'l Appl.	A61L 17/00
2082213	8/1980	United Kingdom	
2218312A	11/1989	United Kingdom	A01K 91/00

Primary Examiner—George F. Lesmes**Assistant Examiner**—Chris Raimund**Attorney, Agent, or Firm**—Hal Brent Woodrow[57] **ABSTRACT**

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

FIG-1

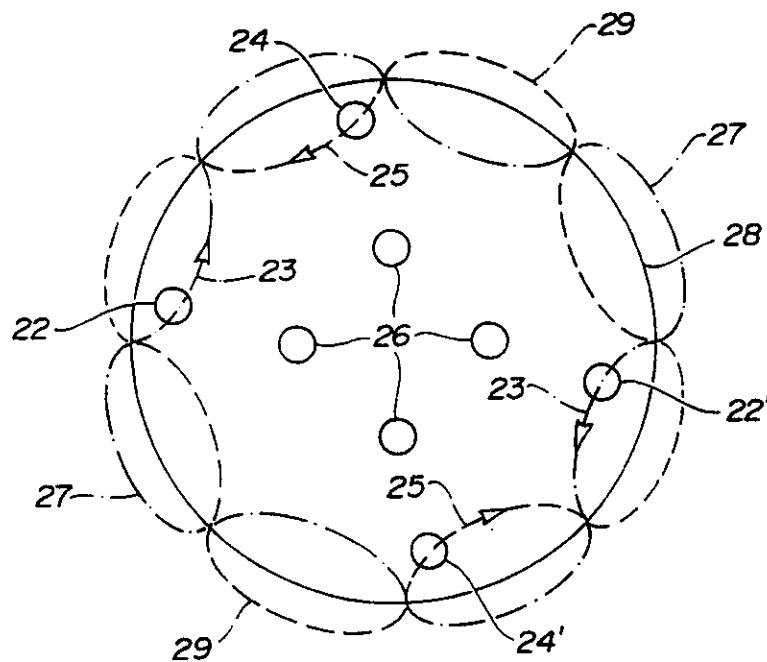


FIG-2

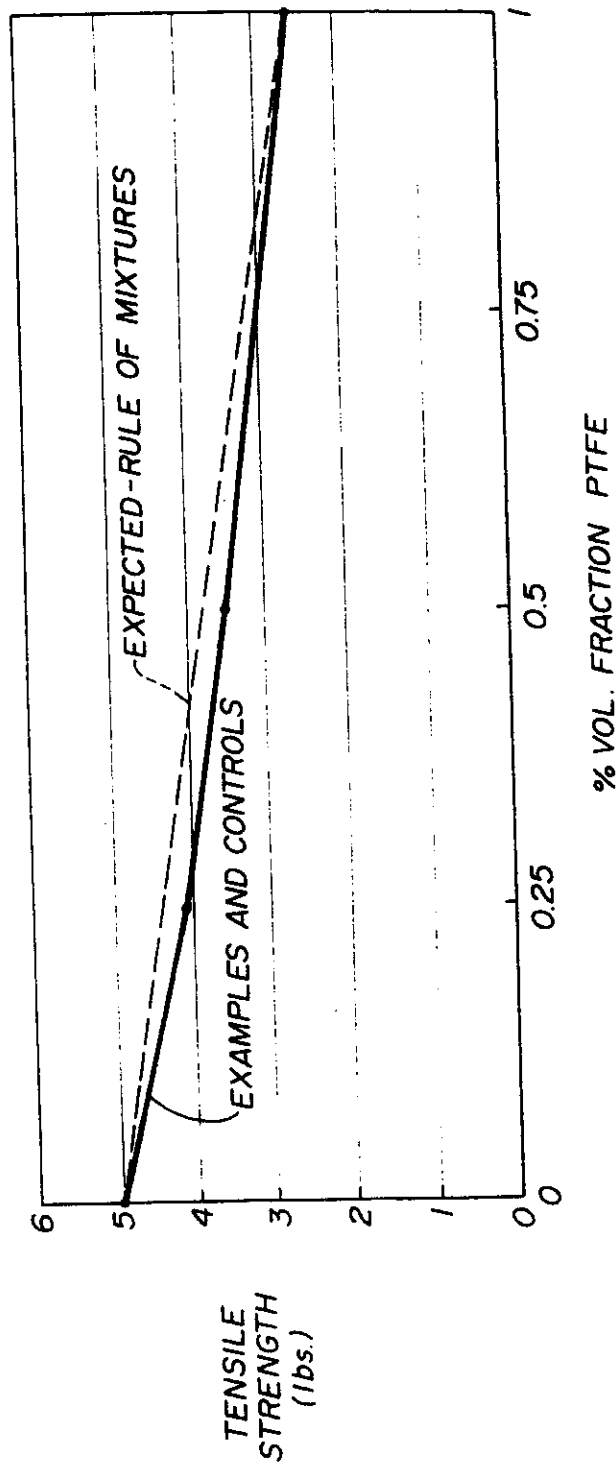
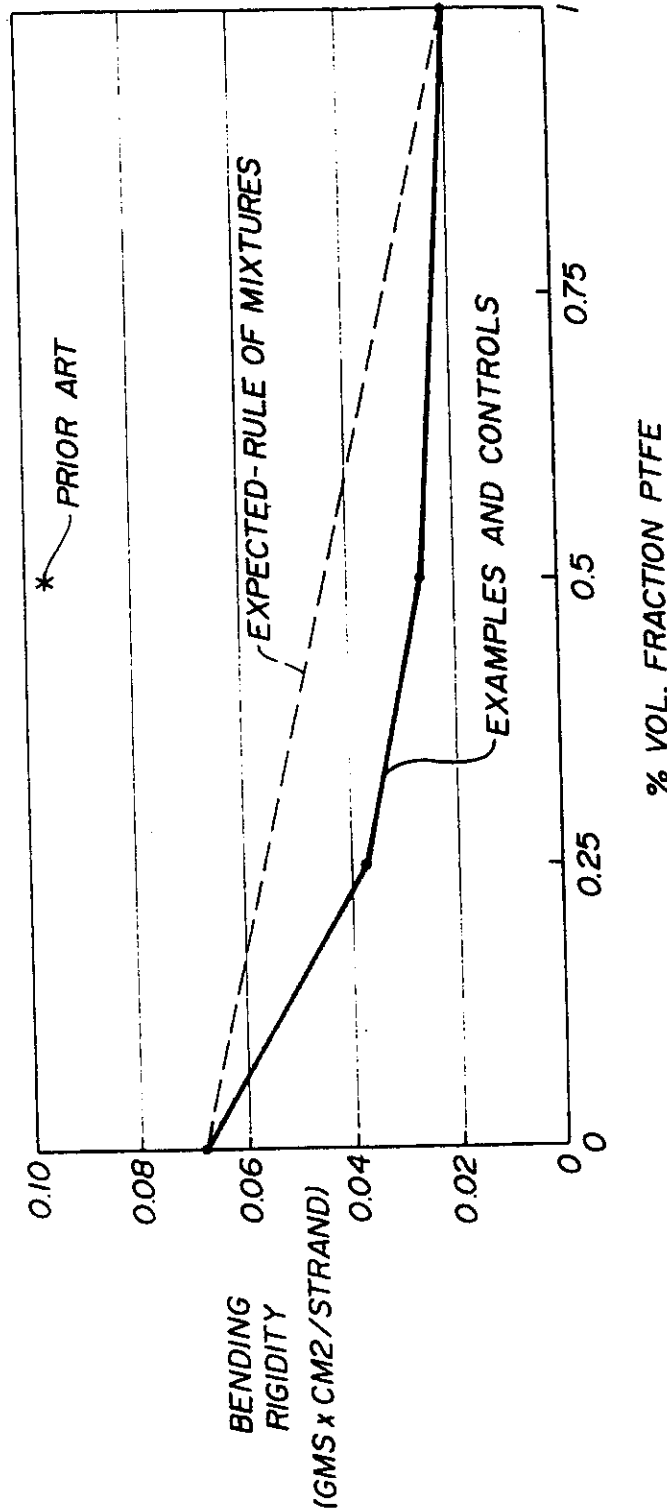


FIG-3



STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutylate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ -caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below),

apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricious polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone,

ε-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluoroethylene copolymers (PETFE), the polychloroethylenes copolymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm ²)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

As may be expected, the tensile strengths of the heterogeneous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c = (Vf_a)(P_a) + (Vf_b)(P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

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24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves

braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricious yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, then the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tying a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tying knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

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- a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and
- b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and
- c) optionally a core.
2. The surgical suture of claim 1 wherein the suture is attached to a needle.
3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.
4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.
5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

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6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.
7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.
8. The surgical suture of claim 1 wherein the second set of yarns is PET.
9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.
10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.
11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.
12. The surgical suture of claim 8 wherein the suture is attached to a needle.

* * * * *



#1 838511

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Alastair Hunter et al.

Serial No.:

Art Unit:

Filed :

Examiner:

For : STERILIZED HETEROGENEOUS BRAIDS

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

The following references are discussed in the Background of the
Invention:

U.S. Patent 3,942,532 (Hunter, et al., issued March 9, 1976).
U.S. Patent 4,624,256 (Messier et al., issued November 25,
1986).

U.S. Patent 3,527,650 (Block, A., issued September 8, 1970).
U.S. Patent 4,470,941 (Kurtz, L., issued September 11, 1984).
WO 86/00020 (Kurtz et al., issued January 3, 1986).

The following additional references may be relevant to the
examination of the above-identified application:

U.S. Patent 3,187,752 (Glick, A., issued June 8, 1965),
discloses a tightly braided nonabsorbable suture coated with a
polymeric silicone.

U.S. Patent 4,043,344 (Landi et al., issued August 23, 1977),
discloses a nonabsorbable suture coated with a polyoxyethylene-
polyoxypropylene copolymer.

VIA EXPRESS MAIL NO. HB346860118
MAILED FEBRUARY 19, 1992

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI000063

U.S. Patent 4,047,533 (Periaccante et al., issued September 13, 1977), discloses an absorbable suture coated with a polyoxyethylene-polyoxypropylene copolymer.


U.S. Patent 4,946,467 (Ohi et al., issued August 7, 1990), discloses a suture having a core of one synthetic fiber material and a covering sheath of silk strands.

U.K. Patent Application GB 2 218 312A, discloses a fishing line of braided construction, some braid filaments being composed of polythene and other filaments composed of polyester and/or nylon.

German Patent DE 2949920, discloses a suture having a core of fibers composed of platinum or gold, and a braided sheath of fibers composed of polytetrafluoroethylene.

A completed Form PTO-1449 and a copy of each cited reference is attached herewith.

Respectfully submitted,


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February 19, 1992

United States Patent [19]

Hunter et al.

[11] 3,942,532

[45] Mar. 9, 1976

[54] BRAIDED SUTURE

[75] Inventors: Alastair Wilson Hunter; Darrell R. Thompson, both of Somerville, N.J.

[73] Assignee: Ethicon, Inc., Somerville, N.J.

[22] Filed: Aug. 15, 1974

[21] Appl. No.: 497,596

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 303,588, Nov. 3, 1972, abandoned.

[52] U.S. Cl.: 128/335.5; 428/375

[51] Int. Cl.: A61L 17/00

[58] Field of Search: 128/335.5; 161/175, 176; 117/139.5 F, 161 R

[56]

References Cited

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3,527,650	9/1970	Block	128/335.5 X
3,694,257	9/1972	Dumont	117/139.5 F
3,754,069	8/1973	Adams et al.	128/335.5 X
3,776,766	12/1973	Smerz et al.	117/139.5 F X
3,839,524	10/1974	Adams et al.	128/335.5 X

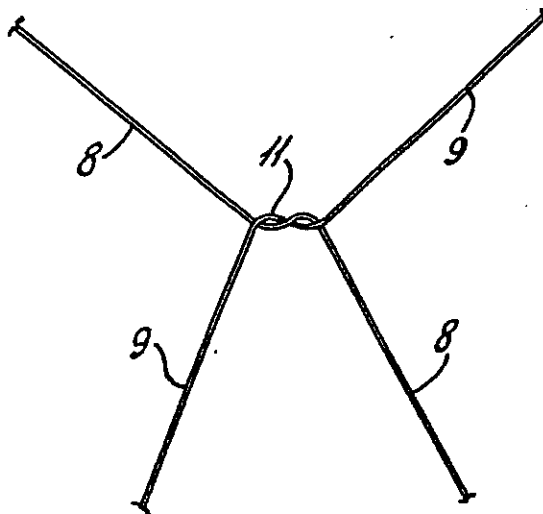
Primary Examiner—Dalton L. Truluck
 Attorney, Agent, or Firm—Wayne R. Eberhardt

[57]

ABSTRACT

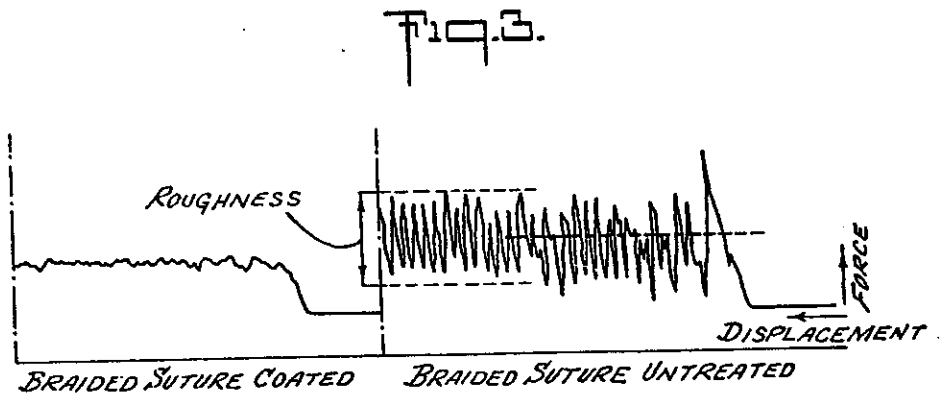
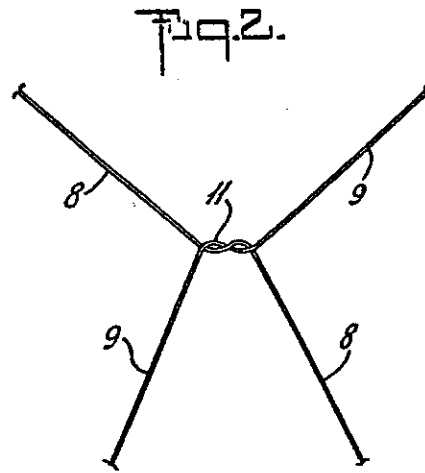
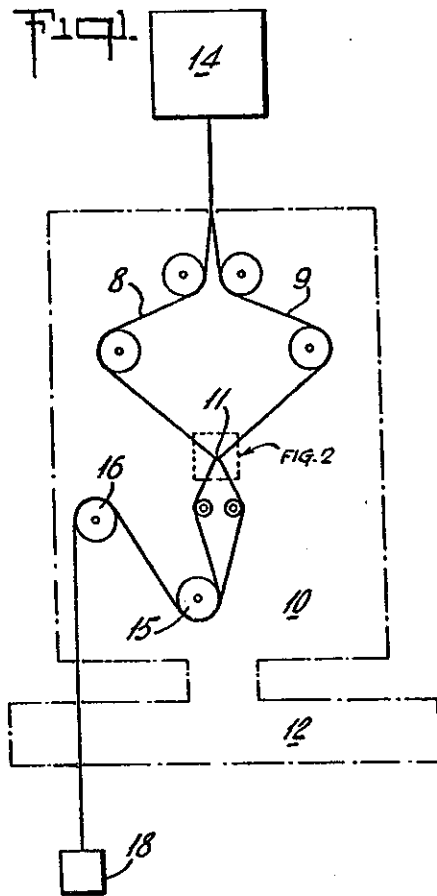
The tie-down characteristics of braided sutures are improved by applying to the surface thereof a polymeric ester of a dibasic acid and a glycol.

16 Claims, 3 Drawing Figures



U.S. Patent March 9, 1976

3,942,532



3,942,532

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BRAIDED SUTURE

BACKGROUND OF THE INVENTION

This application is a continuation-in-part of my co-pending U.S. application Ser. No. 303,588, filed Nov. 3, 1972 now abandoned.

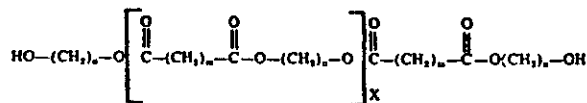
The present invention relates to surgical sutures and more specifically to multifilament sutures. Braided polyester multifilament sutures have been used by many surgeons for their strength and lack of tissue reactivity. Other surgeons prefer to use waxed silk when a non-absorbable suture is required because of its excellent hand, ease of knotting, and ease of passage through tissue.

An important characteristic of sutures in deep wound surgery is the ease of sliding a single throw knot down the suture into place. This behavior, sometimes referred to as the "tie-down performance" may be evaluated subjectively by tying a suture around a suitable mandrel. A single throw knot is formed and while pulling on the two free ends, the knot is forced to slide along the suture. The roughness or smoothness of this sliding action is an important criterion of performance.

Uncoated braids such as a braided polyethylene terephthalate suture give a very rough, jerky behavior while sutures coated with TEFLON, as described in U.S. Pat. No. 3,527,650 and wax-coated braided silk sutures are very smooth. Fortunately, the roughness or smoothness of tie-down can be measured and assigned a numerical value that will enable one to predict performance in the hands of the surgeon without reliance upon the subjective test referred to in the preceding paragraph. A method of using an INSTRON Universal Testing Instrument to determine tie-down performance is described below.

The present invention is directed to improving the tie-down characteristics of a braided suture by applying a surface coating of a non-toxic and physiologically inert polymer that does not adversely affect the hand or tensile properties of the suture.

It has now been discovered that the tie-down performance of braided, twisted, or covered multifilament sutures may be improved (the roughness decreased) by applying to the surface thereof polyesters derived from the polymerization of lactones or obtained by esterifying low molecular weight glycols with a dimeric acid. Preferred coating compositions are polyesters characterized by a melting point above room temperature and have the formula:

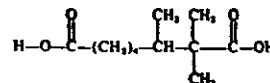


wherein n is an integer larger than 1 and smaller than 13, m is an integer larger than 1 and smaller than 9 and X is the degree of polymerization. Thus, stoichiometric quantities of succinic, glutaric, adipic, pimelic, suberic, azelaic, sebacic acid, or mixtures thereof may be condensed with ethylene glycol, propylene glycol, butanediol, pentanediol, hexanediol, nonanediol, decanediol, undecanediol, dodecanediol, or mixtures thereof to obtain a polyester suitable for application as a surface coating. Polyesters of the above formula having a molecular weight in the range of approximately 1,000 to

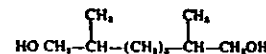
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15,000 and characterized by having at least two carbon atoms between the ester linkages in the polymer chain have been found to give the best lubricant and handling properties on silk and polyester sutures. Particularly preferred polyesters are those derived from 1,4-butanediol ($n=4$) and adipic acid ($m=4$) having a molecular weight of 2,000-3,000.

It will be understood that branched chain acids such as α,α,β -trimethylsuberic acid having the formula:



3,7-dimethyloctadienoic acid; 1,4-cyclohexanecarboxylic acid; mesaconic acid; β,β -dimethyl glutaric acid; and dimer acid; and branched chain diols such as diisobutyl glycol having the formula:

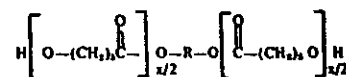


and glycols having a secondary hydroxyl group such as 1,2-propylene glycol may be added to the reaction mixture in small amounts as comonomers to produce polyesters suitable as coating materials that have a melting point above room temperature. The addition of larger amounts of such comonomers to the reaction mixture will result in low melting polyesters that are unsuitable for use in the present invention.

Polyesters that are useful in the manufacture of coated sutures in accordance with the present invention may also be prepared by polymerizing lactones. Such polyesters are characterized by a melting point above room temperature, and have the formula:



wherein n is an integer larger than 2 and X is the degree of polymerization. Particularly preferred is the polyester characterized by a molecular weight of about 2,000 obtained by polymerizing ϵ -caprolactones in the presence of a poly-methylenediol and having the formula:



wherein R is a polymethylene group derived from the poly-methylenediol and x is the degree of polymerization.

The polyester coating compositions described above are non-toxic and may be applied to the multifilament suture from solution. The multifilament suture may be

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of braided, twisted, or covered construction. The construction of a covered suture is described in U.S. Pat. No. 3,791,388. The suture is then air dried to remove solvent and form a continuous surface coating.

The amount of the polyester coating composition applied to the suture may be varied depending upon the suture size and composition. Thus, the surface coating on a size 7/0 braided polyester suture may amount to from about 5 percent to as much as 7 percent of the weight of the suture. Sutures of larger size (size 5/0-5) require a smaller amount of the polyester coating composition (about 0.4 percent to 1 percent based upon the weight of the suture).

The surface coating composition (0.4 percent to about 7 percent based on suture weight) has no detrimental effect on tensile strength or stability. While the application of an excess of the surface coating composition has an effect on lubricity, it may detract from other physical properties of the suture, particularly knot stability.

A numerical value may be assigned to the tie-down performance of any braided suture when tested in accordance with the following procedure. In describing the test for tie-down performance reference is made to the accompanying drawings wherein:

FIG. 1 is a diagrammatic representation of an INSTRON Tester and shows two braided suture strands in position for testing;

FIG. 2 is an enlarged perspective view of the single throw knot illustrated in FIG. 1;

FIG. 3 is a reproduction of the tracing of an oscillographic recorder.

All tie-down measurements reported in the tables are made on a Table-Model INSTRON Tensile Tester using a Type B tension cell, full-scale range 100 to 2,000 grams. The INSTRON instrument is manufactured by the Instron Corporation of Canton, Massachusetts. A high-speed SANBORN Oscillographic Recorder (Model 7702A, manufactured by Hewlett-Packard, Waltham, Massachusetts) is substituted for the standard INSTRON Recorder which would be too slow to follow the rapid changes in force that result as the sutures under test slide against each other. A high-gain DC Amplifier (Hewlett-Packard Model 8803A, manufactured by Hewlett-Packard, Waltham Division, Waltham, Massachusetts) is used to interface this recorder with the INSTRON Transducer and a low-voltage DC power supply is provided to excite the transducer. The measurements are made in an air-conditioned laboratory at 72°F. and 50 percent relative humidity. To hold the specimen suture strands, a line contact jaw is used. The INSTRON machine is operated at a cross-head speed of 50 inches per minute and the chart speed of the oscillographic recorder is 20 millimeters per second.

Subjective tests for tie-down involved the suture configuration 11 shown in FIG. 2 (a single throw knot). The same configuration is produced by a pulley ar-

angement that is supported by a steel plate 10 shown in FIG. 1. The steel plate is attached to the cross-head 12 of the INSTRON Tester.

To perform tie-down measurements, two strands 8 and 9 of the same suture are attached at one end to the B cell transducer 14 of an INSTRON Tester. The sutures are threaded through the pulley arrangement as shown in FIGS. 1 and 2. The other end of the suture strands are brought together, passed around the pulleys 15 and 16, and attached together to a weight 18 which provides tension similar to that applied in a subjective test. A weight of 2.5 pounds is used in the standard procedure.

FIG. 3 shows actual recorder traces for a braided polyethylene terephthalate suture before and after coating with a polymer to improve tie-down performance. The roughness values are measured along the ordinate and throughout the specification and examples are recorded in pounds (roughness). When relatively smooth samples are compared, the amplitude of the oscillographic recorder can be increased by a factor of 20.

The present invention will be further illustrated by the following examples which illustrate preferred embodiments of the inventive idea.

EXAMPLE I

A condensation polymer is prepared by reacting 42.5 weight percent of 1,4-butanediol with 57.5 weight percent of adipic acid. The polymer so obtained is a firm, waxy solid having a viscosity of 1475 cps. at 60°C., a molecular weight of 2150, an acid number of 1.7, and a hydroxyl number of 52.1.

The polyester prepared as described in the preceding paragraph (4.84 parts by weight) is dissolved in 95.16 parts by weight of toluene and the solution is applied to a braided, size 2/0 polyethylene terephthalate suture strand using an ATLAB Yarn Finish Applicator manufactured by Precision Machine & Development Company, P.O. Box 645, New Castle, Delaware. The braid is coated under the following conditions:

Speed of Yarn	30 feet per minute
Hypodermic Syringe Size	30 cc.
Motor Drive Rate	10 r.p.m.
Hysteresis Tension	5 pounds

The coated, braided strand is dried in forced air at 70°-80°F. to evaporate the solvent and is then collected on a take-up drum. No curing of the adipic ester is required. The coating is continuous over the entire surface of the suture and amounts to 1 percent by weight (based on the weight of the untreated suture). The coated braid is sterilized by exposure to cobalt-60 irradiation without significant loss of straight tensile strength or knot strength. The physical characteristics of the braided polyethylene terephthalate suture before and after coating are summarized in Table I.

TABLE I

	Braided Size 2/0 Polyethylene Terephthalate Suture (Untreated)	Braided Size 2/0 Polyethylene Terephthalate Suture (Coated)
Tensile Strength		
Non-Sterile	100,200 p.s.i.	99,100 p.s.i.
Sterile	99,400 p.s.i.	98,800 p.s.i.
Knot Strength		
Non-Sterile	53,900 p.s.i.	53,500 p.s.i.
Sterile	52,100 p.s.i.	55,000 p.s.i.

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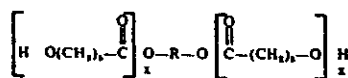
TABLE 1-continued

	Braided Size 2/0 Polyethylene Terephthalate Suture (Untreated)	Braided Size 2/0 Polyethylene Terephthalate Suture (Coated)
Roughness	3.67 lbs.	0.31 lbs.

Similar results are obtained when the polyester resin described in this Example is used to coat braided silk, cotton, and collagen sutures. However, higher levels of coating solids should be used for the hydrophilic substrates such as cotton and silk. The coated sutures made according to this example have excellent knot holding properties.

EXAMPLE II

A linear polymer of ϵ -caprolactone characterized by an average molecular weight of about 2,000 and having the structural formula:



wherein R is a polymethylene group derived from a polymethylenediol and x represents the degree of polymerization, was purchased from the Union Carbide Corporation, Chemical Division, 270 Park Avenue, New York City, New York. This polycaprolactone has a molecular weight of about 2,000 and is sold under the trade name NIAX POLYOL D-560.

The polycaprolactone identified above was dissolved in toluene to obtain a 3.8 percent by weight solution. This solution is applied to a braided, size 2/0 polyethylene terephthalate suture strand using an ATLAB Yarn Finish Applicator. The braid is coated under the conditions as described in Example I above and dried in forced air at 75°F. The coated braid, after evaporation of the solvent is collected on a take-up drum. No curing of the polycaprolactone is required. The coating is continuous over the entire surface of the suture and amounts to 1 percent by weight (based on the weight of the untreated suture). The coated braid is sterilized by exposure to cobalt-60 irradiation without appreciable loss of straight tensile strength or knot strength. The physical characteristics of the braided polyethylene terephthalate suture before and after coating are summarized in Table 2.

TABLE 2

	Braided Size 2/0 Polyethylene Terephthalate Suture (Untreated)	Braided Size 2/0 Polyethylene Terephthalate Suture (Coated)
Tensile Strength		
Non-Sterile	96,300 p.s.i.	92,000 p.s.i.
Sterile	95,100 p.s.i.	91,500 p.s.i.
Knot Strength		
Non-Sterile	53,900 p.s.i.	51,700 p.s.i.
Sterile	54,700 p.s.i.	51,700 p.s.i.
Roughness	2.77 lbs.	0.67 lbs.

Similar results are obtained when the polycaprolactone is used to coat braided silk, cotton, and collagen sutures of size 2/0 through 6/0. The polyesters of the present invention may also be used to coat absorbable synthetic sutures such as those described in U.S. Pat.

No. 3,297,033 and 3,636,956 with a resulting improvement in tie-down characteristics.

What is claimed is:

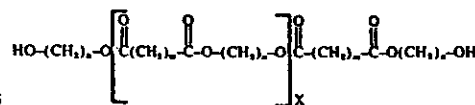
1. A suture having improved tie-down performance comprising a multifilament, the outer surface of the multifilament being coated with from about 0.4 percent to about 7 percent based on suture weight of an aliphatic polyester that is a solid at room temperature; said polyester having from 2 carbon atoms to about 12 carbon atoms between the ester linkages in the polymer chain and said polyester having a molecular weight in the range of 1,000 to 15,000.

2. The suture of claim 1, characterized by a braided construction.

3. The suture of claim 1, characterized by a twisted construction.

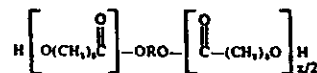
4. The suture of claim 1, characterized by a covered construction.

5. The multifilament suture of claim 1, wherein the polyester has the formula:



wherein n is an integer larger than 1 and smaller than 13, m is an integer larger than 1 and smaller than 9 and X is the degree of polymerization.

6. The multifilament suture of claim 1, wherein the polyester has the formula:



wherein R is a polymethylene group and X represents the degree of polymerization.

7. The multifilament suture of claim 1, wherein the

polyester is a condensate of adipic acid and 1,4-butanediol having a molecular weight of about 2,000-3,000.

8. The suture of claim 7, wherein said multifilament is a silk multifilament and the polyester coating

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amounts to about 5 percent of the weight of the untreated suture.

9. The suture of claim 7, wherein said multifilament is a polyethylene terephthalate multifilament, and the polyester coating amounts to about 1 percent of the weight of the untreated suture.

10. The multifilament suture of claim 6, wherein the polyester coating has a molecular weight of about 2,000.

11. The suture of claim 10, wherein said multifilament is a polyethylene terephthalate multifilament and the polyester coating amounts to about 1 percent of the weight of the untreated suture.

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12. The suture of claim 10, wherein said multifilament is a silk multifilament and the polyester coating amounts to about 5 percent of the weight of the untreated suture.

13. The multifilament suture of claim 1, characterized by a roughness of less than 1 pound.

14. The multifilament suture of claim 2, characterized by a roughness of less than 1 pound.

15. The multifilament suture of claim 3, characterized by a roughness of less than 1 pound.

16. The multifilament suture of claim 4, characterized by a roughness of less than 1 pound.

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United States Patent [19]**Messier et al.**[11] Patent Number: **4,624,256**[45] Date of Patent: **Nov. 25, 1986**[34] **CAPROLACTONE POLYMERS FOR
SUTURE COATING**[75] Inventors: **Kenneth A. Messier, Jewett City;
Joseph E. D. Kham, Old Lyme, both of
Conn.**[73] Assignee: **Pfizer Hospital Products Group, Inc.,
New York, N.Y.**[21] Appl. No.: **774,636**[22] Filed: **Sep. 11, 1985**[51] Int. Cl. **A61L 17/00**[52] U.S. Cl. **128/335.5**[58] Field of Search **132/335.5**[56] **References Cited****U.S. PATENT DOCUMENTS**

3,773,737	11/1973	Gonodomin	128/335.5
3,867,190	2/1975	Schmidt	128/335.5
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3,918,455	11/1975	Coplan	128/335.5
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OTHER PUBLICATIONS**Sagarin, Cosmetics Science & Technology, 1957, pp.
104-105.****Primary Examiner—Gregory E. McNeill
Attorney, Agent, or Firm—Charles J. Knuth; Peter C.
Richardson; Gezina Holtrist**[57] **ABSTRACT****High molecular weight caprolactone polymers are
coated on surgical sutures to improve suture properties
such as smooth surface, single knot slipdown, two
throw knot slipdown for repositioning, and three throw
knot security.****8 Claims, No Drawings**

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CAPROLACTONE POLYMERS FOR SUTURE COATING

BACKGROUND OF THE INVENTION

The invention relates to surgical sutures comprising a braided multifilament of a biocompatible material coated with a lubricating agent. More particularly, the invention relates to sutures coated with high molecular weight polycaprolactone or a high molecular weight copolymer of at least 90% by weight of caprolactone.

Coating of braided sutures with lubricating agents to improve knot slipdown properties is known in the art. For instance, U.S. Pat. No. 4,080,969 discloses coating braided polyglycolic acid filaments with diglycolate polyesters. U.S. Pat. No. 4,027,676 provides a coating for sutures comprising a bioabsorbable film-forming polymer, the bioabsorbable lubricant polyalkylene glycol and a hydrophobic material. U.S. Pat. No. 3,867,190 relates to polyglycolic acid sutures coated with a copolymer of lactic and glycolic acid. This patent also mentions incorporation of caprolactone in glycolide sutures. The formed copolymer contains not more than 15% by weight of caprolactone. Use of such copolymer in coating of sutures is not suggested.

U.S. Pat. No. 3,942,532 describes polyester multifilament sutures coated with polycaprolactone Niox Polyol D-560 having a low molecular weight of about 2,000 and a melt viscosity at 60° C. of 500 centipoise.

It is an object of the invention to provide a suture having a smooth surface, good single knot slipdown, two throw knot slipdown for repositioning, and three throw knot security.

SUMMARY OF THE INVENTION

In accordance with the invention, there is provided a surgical suture of a braided multifilament biocompatible, bioabsorbable material coated with a lubricating agent selected from the group consisting of high molecular weight polycaprolactone, a high molecular weight copolymer derived from at least 90% by weight of caprolactone and the remainder another biodegradable monomer, and a blend of at least 50% by weight of said polycaprolactone or said copolymer and up to 50% by weight of another biodegradable lubricating agent, based on the combined weights of the lubricating agents. The homopolymer or copolymer of caprolactone has a melt viscosity at 60° C. of at least about 50,000 centipoise (cps) or is a solid.

Generally, the lubricating agent or agents are present in an amount of about 0.5 to 10% by weight based on the suture.

The invention also provides for a needled surgical suture wherein a novel coated suture as described above is threaded through or fitted with a surgical needle, and a surgical suture package comprising a sterile enclosure containing a sterile needled coated surgical suture as previously described.

DETAILED DESCRIPTION OF THE INVENTION

According to the invention, any conventional bioabsorbable suture material may be used. Sutures must be biocompatible such that they do not cause any adverse reactions in living tissue. The sutures of the invention are bioabsorbable such that they are slowly absorbed in living tissue. Examples of suitable bioabsorbable suture materials are collagen, poly(glycolic acid), poly(lactic

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acid), poly(hydroxybutyric acid), chitosan, chitin, carboxymethylcellulose etc. Preferably, the suture is made of poly(glycolic acid) or a glycolic acid copolymer containing at least 85% glycolic acid units.

The primary lubricating agent of the invention is high molecular weight polycaprolactone or a high molecular weight copolymer of at least 90% by weight of caprolactone and at most 10% by weight of another biodegradable monomer. Examples of such biodegradable monomers are glycolic acid, a glycolide, lactic acid, a lactide, p-dioxanone, valerolactone and other lactones derived from linear aliphatic hydroxycarboxylic acids, α -hydroxybutyric acid, ethylene carbonate, ethylene oxide, propylene oxide, propylene carbonate, malic acid ester lactones, succinic acid, adipic acid and other linear aliphatic dicarboxylic acids, and linear aliphatic diols such as butanediol and hexanediol.

High molecular weight polycaprolactone may be made by conventional methods for the polymerization of ϵ -caprolactone. Suitable polycaprolactones are commercially available, e.g. PCL-300 and PCL-700 of Union Carbide Corporation, also known by the brand names Tone P-300 and Tone P-700, respectively, having weight average molecular weights of about 15,000 and about 40,000, respectively, as reported by the manufacturer. Copolymers of caprolactone and another monomer may be made by conventional polymerization techniques, e.g. as described in U.S. Pat. No. 4,190,720.

When reference is made hereafter to polycaprolactone, this will include the above-described copolymers of caprolactone containing 10% or less of a biodegradable comonomer.

The high molecular weight polycaprolactone is applied to the multifilament suture generally from a solution in a solvent for polycaprolactone such as methylene chloride. Other known solvents for polycaprolactone may be used such as carbon tetrachloride, chloroform, ethyl acetate, cyclohexanone, methyl ethyl ketone, toluene, and xylene. The concentration of the polycaprolactone in the solvent may range from 1 to 10% by weight based on the solvent. Generally, about 5 g commercially available polycaprolactone per 100 ml of solvent is used. The preferred concentration will provide a readily flowable composition the solvent of which is not difficult to evaporate after the coating is applied, and will deposit the desired amount of polycaprolactone on the suture.

The sutures are immersed in the coating solution for 0.1 to 10 minutes, preferably about 0.2-3 minutes, and air dried at room temperature or, if desired, at slightly higher temperatures. The immersion may be carried out by batch dipping a skein or by continuously passing a continuous length of yarn through the coating solution.

The primary lubricating agent, high molecular weight polycaprolactone, may be mixed with other lubricating agents in an amount of up to 50% by weight of the combined lubricating agents. Examples of such other lubricating agents are poly(ethylene oxide), partially oxidized polyethylene wax, N,N'-ethylene diamine bis-stearamide, C₁₀-C₃₀ fatty acid esters of sterols such as cholesterol and lanosterol, and polyalkylene glycols such as a copolymer of ethylene glycol and propylene glycol.

The coating composition may also contain other components for other purposes including dyes, stabilizers against oxidation or degradation caused by radiation, antibiotics, antiseptics, analgesics, anesthetics, anti-

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inflammatory agents, growth or healing promoting agents and other pharmaceutically active ingredients.

Polycaprolactone is known to be a non-toxic material that degrades slowly in living tissue to form an innocuous metabolizable intermediate.

The following examples illustrate the invention. Examples 1-15 and 20 are comparative examples and Examples 16-19 are examples according to the invention.

EXAMPLES 1-19

Uncoated sutures of polyglycolic acid (18 inch long) were immersed in 100 ml of coating solution. The solvent, percentage by weight of coating material in solution, percentage coating by weight on the coated suture, and the size of the sutures are listed in Table 1.

The sutures were immersed in the coating solution for 2 to 3 minutes and air dried at room temperature. The percentage coating was calculated by weighing the suture on an analytical balance before and after coating and is given in Table 1 as percent of total weight of the coated suture. After air drying, the coated sutures were stored in a desiccator.

TABLE 1

Ex- am- ple	Suture size	Coating material	Solvent	% Coating material in solvent	% Coating on suture
1	2-0	PEO 8000	CH ₂ Cl ₂	3	1.4
2	2-0	PGA powder	CH ₂ Cl ₂	3	1.3
3	2-0	PEO 8000- PGA powder (3:1)	CH ₂ Cl ₂	3.5	1.5
4	2-0	Pluracol P-4010	CHCl ₃	3	1.0
5	3-0	PVP	CHCl ₃	2	6.9
6	3-0	PVP	CHCl ₃	2	1.7
7	3-0	PVA	H ₂ O	3	6.5
8	3-0	PEO 8000- calcium stearate (2:1)	CH ₂ Cl ₂	3	3.4
9	2-0	Petrac 15	CHCl ₃	5	3.5
10	2-0	Petrac 165	CHCl ₃	5	2.9
11	2-0	PEG-100 stearate	CH ₂ Cl ₂	5	4.4
12	2-0	PEG-40 stearate	CH ₂ Cl ₂	5	3.9
13	2-0	Carnauba wax	CHCl ₃	5	3.9
14	2-0	Kemamide W-40	CHCl ₃	5	2.3
15	4-0	Cholesteryl palmitate	CHCl ₃	5	2.5
16	1-0	PCL (Tone P300)	CH ₂ Cl ₂	5	5.7
17	1-0	PCL (Tone P700)	CH ₂ Cl ₂	5	4.1
18	1-0	PCL (Tone P700) Super Sterol Ester (1:1)	CH ₂ Cl ₂	5	2.4
19	1-0	PCL (Tone P700) Super Sterol Ester (4:1)	CH ₂ Cl ₂	5	3.1

The abbreviations and trademarks in Table 1 stand for the following:

PEO: poly(ethylene oxide)
PGA: poly(glycolic acid)
Pluracol P-4010: poly(propylene glycol)
PVA: poly(vinyl pyrrolidone)
Petrac 165: wax
Petrac 215: partially oxidized polyethylene wax (Petrochemicals Company Inc.)
PEO: poly(ethylene glycol)
Kemamide: N,N'-ethylene diamine bis-stearamide
PCL: polycaprolactone
Super Sterol Ester: cholesterol and lanosterol esters of a mixture of C₁₀-C₁₈ fatty acids esters, supplied by CRODA Inc.

The melt viscosity of PCL (Tone P300) was measured with a Brookfield RVT viscometer having a No. 7 spindle at 20 and 50 rpm. The polymer was melted in a beaker and surrounded by a temperature controlled water bath, the temperature of which was measured

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with an electronic thermometer sensitive to $\pm 0.1^\circ \text{C}$. The viscosity was 51,200 cps at 60°C . PCL (Tone P700) is solid at 60°C . The molecular weight of PCL (Tone P700) was determined by gel permeation chromatography and was found to be 100,000 (polystyrene equivalent in dichloromethane).

Table 2 sets out the properties of the coated sutures of Table 1.

The general texture and feel of a suture such as flexibility, smoothness and hardness was observed by handling the suture and drawing between fingers. Typical observations as set out in Table 2 are stiff, silky, waxy.

The slipdown property of a suture was determined by tying tightly a two-throw square knot, then grasping the long ears and pulling apart. If the suture was drawn through the knot, giving the appearance of the knot slipping down the braid, it was marked as excellent (exc.), good, or acceptable (acc.) depending on the ease of slipdown. If the knot seized or was difficult to slip down, the suture was marked as locks, poor, or rachety, depending on the difficulty of slip down.

The slipdown property was also tested under wet conditions by immersion of the unknotted suture in water for 5 seconds and immediately testing thereafter.

The knot security of a suture was tested by tying firmly a triple throw square knot and pulling the suture from a patient's side until the knot slipped or the suture broke. If the knot slipped, knot security was marked poor. If the suture broke without slip, the knot was sufficient to hold the suture at the knot and was marked acceptable in Table 2.

The knot security was tested under wet conditions by immersion of the unknotted suture in water for 5 seconds and immediately testing thereafter.

The wet knot slipdown was tested by tying tightly a two-throw granny knot and slipping down the knot. The knot was then wetted by rubbing with fingers dipped in water. An attempt was then made to slip the knot down further. If the knot slipped both dry and wet, the suture was marked as acceptable, good, or excellent depending on the ease of the slip. If the knot slipped dry but not wet, the suture was marked as locking. If the slip was poor wet and dry and locking was difficult to determine, the suture was marked poor, or rachety.

TABLE 2

Ex- am- ple	Texture	2 throw square slipdowns		3 throw square slipdowns		2 throw granny slip- down, wet	Comments
		dry	wet	dry	wet		
1	stiff	exc.	poor	acc.	acc.	locks	exc. dry, poor wet
2	powdery smooth	poor	locks	acc.	acc.	locks	poor lubr. overall
3	wiff	exc.	poor	acc.	acc.	locks	exc. dry, poor wet
4	silky	acc.	acc.	acc.	acc.	locks	acc. lubr. but locks
5	very stiff	poor	locks	acc.	acc.	locks	very poor lubr., locks as 5
6	very stiff	locks	locks	acc.	acc.	locks	
7	stiff, rough	rich-	locks	acc.	acc.	poor	poor lubr. esp. wet
8	silky	exc.	poor, rachety	acc.	acc.	locks	exc. slip-down dry, but not when wet

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TABLE 2-continued

Ex- am- ple	Texture	2 throw square slipdown		3 throw square slipdown		2 throw grassy slip- down, wet	Knot	Comments
		dry	wet	dry	wet			
9	stiff, rough	exc.	exc.	acc.	acc.	exc., no locking		excellent
10	very rough	rach- ety	rachety	acc.	acc.	rachety		poor lubr., not affected by water
11	stiff, waxy	very good	good	acc.	acc.	rachety		fairly good, not much affected by water
12	stiff, smooth	rach- ety	rachety	acc.	acc.	rachety		poor lubr., not affected by water
13	rough	fine to rach- ety	good	acc.	acc.	acc.		rachety dry, good wet
14	waxy, rough	good	good	acc.	acc.	good		good, not affected by water
15	rough	poor	poor	acc.	acc.	poor		poor lubr. overall as 14
16	stiff, waxy	exc.	exc.	acc.	acc.	exc.		as 14
17	stiff, waxy	exc.	exc.	acc.	acc.	exc.		as 14
18	silky, good feel	exc.	exc.	acc.	acc.	exc.		exc. good feel, good lubr., not affected by water
19	stiff	exc.	exc.	acc.	acc.	exc.		as 18.

"lubr.": lubricant

COMPARATIVE EXAMPLE 20

An uncoated suture of polyglycolic acid (34 inch long), size 3-0 was immersed in 100 ml of coating solution comprising 95.0 ml methylene chloride and 5.00 g of Tone polyester 0240 (formerly Niox Polyol D560) of Union Carbide Corporation. The manufacturer specifies a molecular weight of 2000 and a viscosity of 500 cps at 60° C. for Tone polyester 0240. The coating solution was obtained by dissolving the Tone polyester 0240 at room temperature in a 200 ml beaker in 3 minutes using a magnetic stirrer.

The suture was immersed in the coating solution for one minute and air-dried at room temperature. The % coating on the suture was 5.9.

Knot slip and knot security were determined as follows.

Knot	Result
2 throw square slip down	slips about 0.5 inch. locks and breaks
3 throw square slipdown	locks

-continued

Knot	Result
2 throw grassy slipdown (dry)	acceptable slip
2 throw grassy slipdown (wet)	acceptable slip

I claim:

1. A surgical suture comprising a braided multifilament of poly(glycolic acid or a copolymer containing at least 85% glycolic acid units coated with a lubricating agent selected from the group consisting of a high molecular weight homopolymer of caprolactone, a high molecular weight copolymer of at least 90% by weight of caprolactone and the remainder another biodegradable monomer, and a blend of at least 50% by weight of said homopolymer of said copolymer of caprolactone and up to 50% by weight of another biodegradable lubricating agent, said homopolymer or copolymer of caprolactone having a melt viscosity at 60° C. of at least about 50,000 centipoise or being solid.

2. A suture according to claim 1 wherein said other biodegradable lubricating agent is a mixture of sterol esters of C₁₀-C₃₀ fatty acids.

3. A suture according to claim 2 wherein said sterol is a mixture of cholesterol and lanosterol.

4. A suture according to claim 1 wherein said lubricating agent is present in an amount of 0.5 to 10% by weight based on the weight of the suture.

5. A needled surgical suture comprising at least one filament of poly(glycolic acid) or a copolymer containing at least 85% glycolic acid units coated with a lubricating agent selected from the group consisting of a high molecular weight homopolymer of caprolactone, a high molecular weight copolymer of at least 90% by weight of caprolactone and the remainder another biodegradable monomer, and a blend of at least 50% by weight of said homopolymer or said copolymer of caprolactone and up to 50% by weight of another biodegradable lubricating agent, said homopolymer or copolymer of caprolactone having a melt viscosity of 60° C. of at least about 50,000 centipoise.

6. A needled surgical suture according to claim 5 wherein said other biodegradable lubricating agent is a mixture of sterol esters of C₁₀-C₃₀ fatty acids.

7. A surgical suture package comprising a sterile enclosure containing a sterile needled surgical suture, the suture comprising at least one filament of poly(glycolic acid) or a copolymer containing at least 85% glycolic acid units coated with a lubricating agent selected from the group consisting of a high molecular weight homopolymer of caprolactone, a high molecular weight copolymer of at least 90% by weight of caprolactone and the remainder another biodegradable monomer, and a blend of at least 50% by weight of said homopolymer of said copolymer of caprolactone and up to 50% by weight of another biodegradable lubricating agent, said homopolymer or copolymer of caprolactone having a melt viscosity at 60° C. of at least about 50,000 centipoise or being solid.

8. A package according to claim 7 wherein said other biodegradable lubricating agent is a mixture of sterol esters of C₁₀-C₃₀ fatty acids.

United States Patent Office

3,527,650

Patented Sept. 8, 1970

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3,527,650
**SUTURE COATING OF POLYETHYLENE OR
 POLYTETRAFLUOROETHYLENE**
 Edward A. Block, Somerville, N.J., assignor to Ethicon,
 Inc., a corporation of New Jersey
 No Drawing. Filed Dec. 21, 1967, Ser. No. 692,283
 Int. Cl. A61B 17/00
 U.S. Cl. 117—7 8 Claims

ABSTRACT OF THE DISCLOSURE

The hand and lubricity of a braided polyethylene terephthalate suture are improved by applying to the surface thereof polymers of polyethylene or polytetrafluoroethylene having a lower coefficient of friction than the suture and a styrene-acrylic ester copolymer resin binder therefor.

The present invention relates to nonabsorbable surgical sutures and more specifically to braided multifilament sutures of polyethylene terephthalate. Braided polyethylene terephthalate sutures have been used by many in the surgical profession for years and actually are preferred over silk by many surgeons for their strength and lack of tissue reactivity. Other surgeons prefer to use waxed silk when a nonabsorbable suture is required because of its excellent hand, ease of knotting, and ease of passage through tissue.

It is a known disadvantage of polyethylene terephthalate sutures that the knot may slip unless repeated knots are tied. Attempts have been made to improve the knotability of polyethylene terephthalate by modifying the surface thereof to decrease lubricity. One method of doing this is described in U.S. Pat. No. 3,307,971, which issued to Leonard D. Kurtz in March of 1967.

The present invention is directed to increasing the lubricity of a braided polyethylene terephthalate suture by applying a surface coating of a nontoxic and physiological inert resin that has a lower coefficient of friction than the polyethylene terephthalate, such as, polytetrafluoroethylene or polyethylene.

Polytetrafluoroethylene has been applied to braided polyethylene terephthalate sutures for the purpose of filling the interstices of the braided structure and achieving the characteristics of a solid monofilament. U.S. Pat. No. 3,322,125 described in Example I impregnating a braided 4/0 polyethylene terephthalate suture with a suspension of polytetrafluoroethylene particles having a particle size of about 0.2 micron. The suture is dried and stretched at 450° F. whereby the particles of polytetrafluoroethylene are trapped within the body of the suture.

The process described in U.S. Pat. No. 3,322,125, however, does not produce a satisfactory surface coating of polytetrafluoroethylene because the polytetrafluoroethylene particles do not adhere to the surface of the suture material. The particles can flake off and produce foreign body reactions near the suture site. It has now been discovered that polytetrafluoroethylene and other resinous particles having a coefficient of friction lower than that of the braided polyethylene terephthalate surface may be cemented to the surface of the braided polyethylene terephthalate suture with a binder resin which prevents flaking of the resinous particles.

Binder resins that are suitable for use in securing polytetrafluoroethylene and similar resinous particles having a lower coefficient of friction than polyethylene terephthalate to the surface of a braided polyethylene terephthalate suture are the non-ionic, self-cross linking, or cross-linkable acrylic polymers, such as Rhoplex HA-12 and Rhoplex B-15, manufactured by Rohm and Haas Company, Philadelphia, Pa., and the thermoplastic acrylic

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polymers, such as Hycar 2601, manufactured by B. F. Goodrich Chemical Company of Cleveland, Ohio and copolymers of an acrylic ester and styrene, such as Aerotex Resin 134, manufactured by the American Cyanamid Company, Bound Brook, N.J.

In the practice of the present invention, a braided polyethylene terephthalate suture is passed through an aqueous mixed dispersion of an acrylic latex of the type identified above and polytetrafluoroethylene particles or polyethylene particles. The ratio of acrylic latex to polytetrafluoroethylene particles in the dispersion is about 1:3 but may be increased to improve the adhesion of the lubricating particles to the surface of the suture or decreased to increase the lubricity of the surface coating. The dwell time of the braided suture with the polytetrafluoroethylene dispersion is just sufficient to coat the surface as penetration of the lubricant particles into the interstices of the suture is not necessary or desired. The braided polyethylene terephthalate after it leaves the coating bath is dried and heat cured. The structure of the braided polyethylene terephthalate suture is altered by the shrinkage that occurs during the curing process. To restore the original close braided structure and control the size (diameter), the coated, braided suture after cooling is heated and stretched under tension. The coated, braided strand may be conveniently heated by moving it one or more times past a steel plate maintained at a temperature between 350° F. and about 440° F. at the rate of 50 to 100 yards per minute. The smaller size sutures, e.g., size 6/0, may be stretched in this manner about 25 percent to 40 percent. The larger sutures, e.g., size 2, are stretched as much as 40 percent to 60 percent.

It is an important aspect of the present invention that the binder resin is flexible and bound to the braided suture in such a manner that it does not crack, flake, or come off of the suture during the heat-stretching step.

The product so obtained has an improved hand and surface lubricity. Yet the knot will not slip if a double square knot is tied. The surface lubricity of a coated polyethylene terephthalate suture may be demonstrated by the following test:

To the cross bar of an Instron tester is secured a 3/4" pulley and a 2" pulley. Using a B cell and the associated upper jaw (red), the instrument is calibrated with a 100 gram weight on the B cell clamp to full scale deflection on the $\times 1$ scale.

To determine the surface lubricity of a coated strand, a 45" length of suture is clamped in the center of the upper jaw; the free end is passed counterclockwise around the 3/4" diameter pulley, and a counterclockwise single throw is made approximately 1 1/2" above the face of the 3/4" diameter pulley wheel. The free end of the suture is then passed over the 2" diameter pulley wheel and secured to a 50 gram weight. The distance from the periphery of the pulley face to the bottom of the B cell clamp is 2 1/2".

In operation, the $\times 10$ scale on the Instron tester is used (1,000 grams full scale) and the crosshead speed and chart speed are 20" per minute.

As the suture passes over itself, a curve is plotted on the graph paper. Since a braided suture has braid protrusions and is somewhat elliptical in cross-section, a smooth curve does not appear. The "stick" portion of a stick-slip curve is produced when it is easier for the suture to stick to itself and elongate than to slip. As the suture is elongated more and more, the tension continues to build up until either the yield point of the suture is reached or until the cohesive force is overcome and the suture slips. This cycle is repeated producing a saw-tooth pattern on the chart.

The surface lubricity of the braided suture may be determined from the maximum and minimum friction

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peaks on the graph in accordance with the following equation:

average lubricity = minimum peak

$$+ \frac{(\text{maximum peak} - \text{minimum peak})}{2}$$

The lubricity of the surface as determined by the test described above may be confirmed subjectively (by feel).

Microscopic examination of the surface coated braided sutures confirms that the surface coating does not scuff or flake off on tie-down.

The invention will be understood from the following examples which illustrate preferred embodiments of the inventive idea.

EXAMPLE I

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0¹, passed beneath two nylon rollers immersed in a trough containing a polytetrafluoroethylene resin dispersed in a thermosetting acrylic latex (Emralon 312, manufactured by Acheson Collids Company, Port Huron, Mich.). The polytetrafluoroethylene resin constitutes about 50 percent of the total resin solids. The braided multifilament moves through the trough at the rate of about 16 yards per minute, the surface of the skein being in contact with the liquid dispersion for about 0.6 to 0.9 seconds. The concentration of resin solids in the trough was maintained at 50±5 percent throughout the run.

After coating, the skein is heated in an oven for ½ hour at 300° F. and heat stretched 40 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating amounting to 3 percent of the total suture weight.

The surface lubricity, as measured by the Instron surface lubricity test described above, is 500 grams. The coated suture does not slip when tied with a double square knot.

EXAMPLE II

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is coated by passing it through one foot in length that contains a resinous dispersion having the following composition:

	Parts
Acrylic resin 45 percent solids (Rhoplex HA-12)	707
Polytetrafluoroethylene resin 60 percent solids (Teflon 30 manufactured by E. I du Pont de Nemours and Company, Inc., Wilmington, Del.)	1,588
Water	7,705

The skein moves through the trough at a speed of 20 feet per minute and is heated in an oven for ½ hour at 300° F. and heat stretched 35 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating amounting to 3.8 percent of the total suture weight. The surface lubricity, as measured by the Instron surface lubricity test described above, is 550 grams. The coated suture does not slip when tied with a double square knot.

EXAMPLE III

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is passed beneath two nylon rollers immersed in a trough containing 340 parts of a polytetrafluoroethylene resin containing 60 percent resin solids and 151 parts of a thermosetting acrylic latex

¹ Diameter 10-13 mils as determined by the method described at p. 918 of the U.S. Pharmacopoeia, vol. XVII.

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(45 percent solids). The acrylic latex is an interpolymer of 90 parts of 2-ethylhexyl acrylate, 12 parts glycidyl acrylate, 90 parts styrene, and 8 parts methacrylic acid. The braided multifilament moves through the trough at the rate of about 16 yards per minute, the surface of the skein being in contact with the liquid dispersion for about 0.6 to 0.9 second.

After coating, the skein was heated in an oven for ½ hour at 275° F. and heat stretched 45 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating amounting to 2.6 percent of the total suture weight.

The surface lubricity, as measured by the Instron surface lubricity test described above, is 530 grams. The coated suture does not slip when tied with a double square knot.

EXAMPLE IV

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is coated by passing it through a trough one foot in length that contains a resinous dispersion having the following composition:

	Parts
Acrylic resin 46 percent solids (Rhoplex B-15)	832
Polytetrafluoroethylene resin 60 percent solids (Teflon 30)	1,868
Water	7,300

The skein moves through the trough at a speed of 20 feet per minute and is heated in an oven for ½ hour at 300° F. and heat stretched 50 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating. The surface lubricity, as measured by the Instron surface lubricity test described above, is 490 grams. The coated suture does not slip when tied with a double square knot.

EXAMPLE V

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is passed beneath two nylon rollers immersed in a trough containing 1,494 parts of a tetrafluoroethylene resin containing 60 percent resin solids (Teflon 30); 1,192 parts of a styrene acrylate copolymer resin latex (Aerotex Resin 134); and 7,314 parts of water. The braided multifilament moves through the trough at the rate of about 20 feet per minute.

After coating, the skein was heated in an oven for ½ hour at 300° F. and heat stretched 55 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating amounting to 3.94 percent of the total suture weight.

The surface lubricity, as measured by the Instron surface lubricity test described above, is 466 grams. The coated suture does not slip when tied with a double square knot.

EXAMPLE VI

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is coated by passing it through a trough one foot in length that contains a resinous dispersion having the following composition:

	Parts
Polyethylene resin 50 percent solids Valsol K070 manufactured by Valchem Chemical Division of United Merchants and Manufacturers, Inc., New York, N.Y.	126
Acrylic resin (45 percent solids) (Rhoplex HA-12)	126
Water	748

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5 The skein moves through the trough at a speed of 20 feet per minute and is heated in an oven for 1/2 hour at 300° F. and heat stretched 40 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating amounting to 3.3 percent of the total suture weight. The dry straight tensile strength is 9.1 pounds, and the dry knot strength is 6.4 pounds. The coated suture does not slip when tied with a double square knot.

EXAMPLE VII

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is coated by passing it through a trough one foot in length that contains a resinous dispersion having the following composition:

	Parts
Polyethylene resin 30 percent solids Valspex N-123 manufactured by the Valchem Division of United Merchants and Manufacturers, Inc., New York, N.Y.	3,375
Non-crosslinking acrylic resin (Hycar 2601)	675
Water	5,950

The skein moves through the trough at a speed of 20 feet per minute and is heated in an oven for 1/2 hour at 300° F. and heat stretched 45 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating amounting to 3.5 percent of the total suture weight.

EXAMPLE VIII

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is coated by passing it through a trough one foot in length that contains a resinous dispersion having the following composition:

	Parts
Acrylic resin 50 percent solids (Hycar 2601)	720
Polytetrafluoroethylene resin 60 percent solids (Teflon 30)	1,868
Water	7,412

The skein moves through the trough at a speed of 20 feet per minute and is heated in an oven for 1/2 hour at 300° F. and heat stretched 40 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating. The surface lubricity, as measured by the Instron surface

lubricity test described above, is 553 grams. The coated suture does not slip when tied with a double square knot.

The invention described and illustrated herein before and secured by this Letters Patent is defined in the following patent claims.

What is claimed is:

1. A braided polyethylene terephthalate suture having a surface coating of a first resin selected from the group consisting of tetrafluoroethylene and polyethylene and a second binder resin comprising a styrene-acrylic ester copolymer, the weight ratio of said first resin to said second resin being between about 1:1 and about 3:1.

2. The suture of claim 1, wherein said first resin is polytetrafluoroethylene.

3. The suture of claim 1 wherein said acrylic ester copolymer is a copolymer of 2-ethylhexyl acrylate.

4. The suture of claim 1, wherein said first resin is polyethylene.

5. A method of improving the hand and surface lubricity of a braided polyethylene terephthalate suture comprising the steps of immersing the suture in an aqueous dispersion of a first resin selected from the group consisting of tetrafluoroethylene and polyethylene and a second binder resin comprising a styrene-acrylic ester copolymer, the weight ratio of said first resin to said second resin being between about 1:1 and about 3:1, for a time sufficient to wet the surface of said suture but not sufficient for said resins to substantially penetrate into the interstices of said suture, drying the suture, curing the binder resin, and heating and stretching the suture at an elevated temperature, whereby a resinous coating is formed on the surface of the suture.

6. The method of claim 5, wherein said first resin is polytetrafluoroethylene.

7. The method of claim 5, wherein said suture is heated at about 300° F. for about one-half hour.

8. The method of claim 5, wherein said first resin is polyethylene.

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ALFRED L. LEAVITT, Primary Examiner

A. GRIMALDI, Assistant Examiner

U.S. CL. X.R.

117-138.8, 139.5, 161; 128-335.5

United States Patent [19][11] Patent Number: **4,470,941****Kurtz**[45] Date of Patent: **Sep. 11, 1984****[54] PREPARATION OF COMPOSITE SURGICAL SUTURES**[75] Inventor: **Leonard D. Kurtz, Woodmere, N.Y.**[73] Assignee: **BioResearch Inc., Farmingdale, N.Y.**[21] Appl. No.: **384,245**[22] Filed: **Jan. 2, 1982**[51] Int. Cl.² **B29B 3/02**[52] U.S. Cl. **264/136; 128/335.5;****264/108; 264/134; 264/171; 264/174;****264/288.8; 264/290.5; 264/345**[58] Field of Search **428/397, 375, 372;****425/113, 192 R; 264/174, 562, 108, 288.8,****134-137, 345, 210.8, 290.5, 171, 210.7;****128/335.5**

[56]

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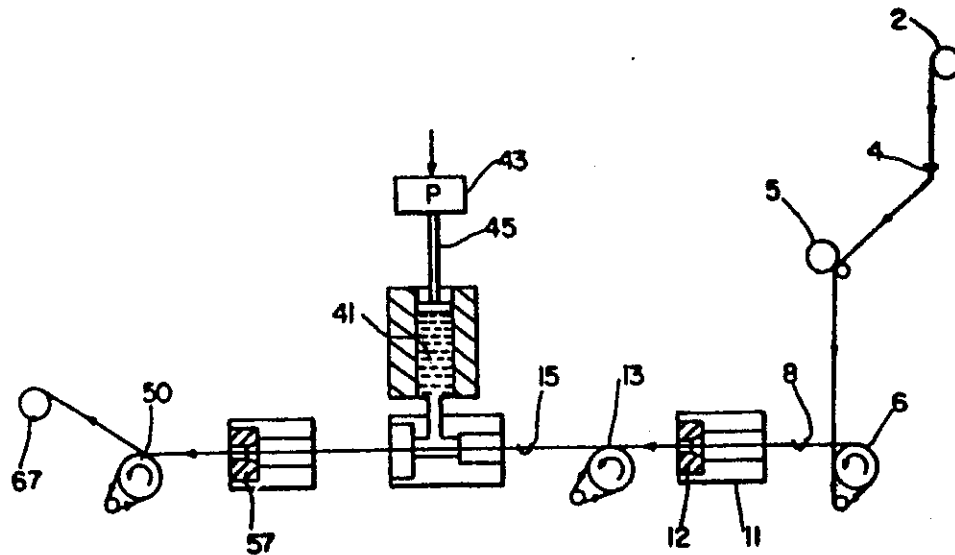
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*Primary Examiner—Jeffery Thurlow**Attorney, Agent, or Firm—Larson and Taylor*

[57]

ABSTRACT

Composite sutures of dissimilar synthetic polymer materials are prepared by forming a thread comprised of a plurality of fibers of a first synthetic polymer, said thread further comprising a second synthetic polymer in intimate association with and present uniformly along the length of said first synthetic polymer, and then applying pressure to the softened polymer to redistribute it throughout the plurality of fibers, and into the interstices thereof and sterilizing the thread to form a suture thereof.

33 Claims, 2 Drawing Figures

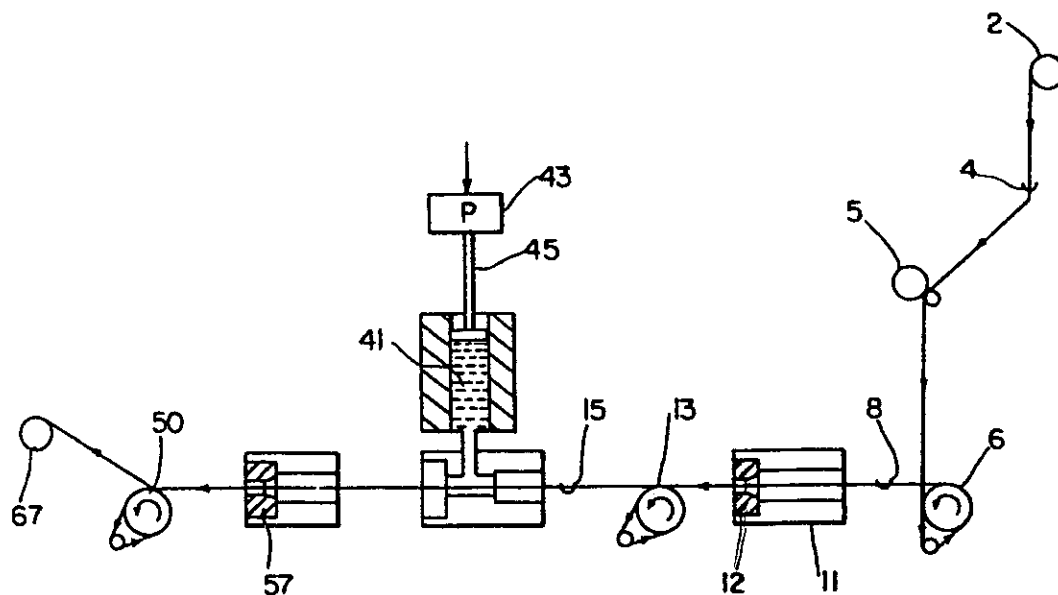


FIG. 1

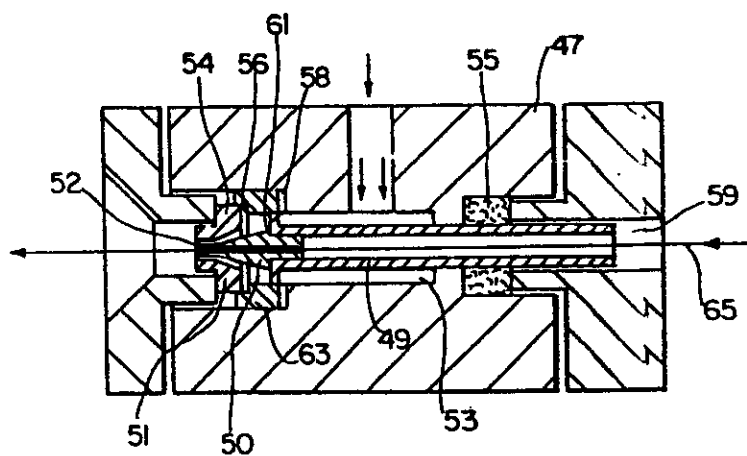


FIG. 2

PREPARATION OF COMPOSITE SURGICAL SUTURES

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a method for preparing composite surgical sutures. More particularly, the invention is directed to methods by which composite sutures of improved lateral strength are obtained.

2. Brief Description of the Prior Art

Composite sutures offer a number of advantages recognized by the prior art. For instance, there are many synthetic fibers which per se are unsuitable for use in sutures because they lack one or more of the properties required in surgical sutures but which possess, nevertheless, certain other properties considered desirable in sutures. By way of example, fibers drawn from many synthetic polymers are too stiff and do not satisfy the knottability requirements of sutures. At the same time these synthetic polymers may possess a tensile strength that renders their use in sutures highly desirable. It is not surprising, therefore, that there have been numerous attempts to combine the best properties of different synthetic materials by compositing them in various ways. These compositing attempts have not been without shortcomings, however.

The principal difficulties involved in the preparation of composite sutures have resided in the fact that polymers whose properties render them desirable for compositing often lack cohesiveness for one another and are otherwise unable to adhere to each other. Many have attempted to remedy these problems by resorting to chemical adhesion through reactive groups provided the polymer components and/or chemical additives to assist in the binding of one polymer component to the other. These techniques, in addition to being costly have in large part proved unsuccessful.

Other attempts to integrate multi-components strands in the production of strings for athletic rackets has been described, for example, in U.S. Pat. No. 4,275,117 to Steven J. Crandall and involves subjecting a fibrous strand composed of fibrous materials having differing melting points to heating conditions sufficient to melt some but not all of the fibrous materials. While perhaps satisfactory for tennis string production or the like, this method of forming composites, as in the case of other aforementioned prior art methods, provides unsatisfactory surgical sutures in that they are found to possess poor lateral strength manifested by a lack of stability against abrasion, kinking and fibrillation during knotting.

Accordingly, it is an object of the present invention to provide a method whereby composite sutures of synthetic polymers having improved lateral strength, that is, composite sutures stabilized against abrasion, kinking and/or fibrillation during knotting are obtained.

Yet another object of the invention is to provide a method of enabling preparation of composite sutures whose surface characteristics, tensile strength and/or knot strength can be tailored to desired specifications.

A further object of the invention is to provide a method of preparing a composite suture whereby one synthetic polymer is tenaciously anchored to the other without the use of chemical adhesion, chemically reactive groups or additives to bind one polymer to the other.

A still further object of the invention is to provide a method for composite suture preparation which enables the use of synthetic fibers heretofore unsuitable for use in suture manufacture.

Another subject of the invention is to provide a method of manufacturing a composite suture having monofilament characteristics which is free of flaking on its outer surface and which retains in large part the flexibility, knottability, knot retention and tensile strength that characterizes multifilament sutures.

SUMMARY OF THE INVENTION

These and other objects of the invention are obtained by forming a thread having interstices therein, comprised of a plurality of fibers of a first synthetic polymer, said thread further comprising a second synthetic polymer in intimate association with and present along the length of at least one of said plurality of fibers, softening said second synthetic polymer to cause flow thereof, applying sufficient pressure to the softened polymer for a time sufficient to redistribute it throughout the plurality of fibers of said first synthetic polymer and into the interstices thereof.

Absolutely essential to the construction of the composite sutures is the pressure step of the method for without it composite sutures having acceptable lateral strength are not obtained. The pressure can be applied to the softened polymer component of the thread in a suitable way with the only proviso being that sufficient pressure be used for a time sufficient to redistribute the softened polymer throughout the fibers of the first synthetic polymer and substantially fill the voids in the thread. According to one preferred embodiment of the invention the pressure is applied by placing the thread under tension during the softening operation. Another preferred method by which the pressure can be applied in the method of the invention is to pass the thread immediately after the softening operation through a compression die having a reduced diameter relative to that of the diameter of the thread so that the necessary pressure can be applied. Although unnecessary, it is preferred in the latter case to use a compression die heated to above the melting point of the polymer component softened. If desired, both forms of pressure application can be utilized as by first effecting the pressure by placing the thread under tension followed by passing the thread through the compression die of reduced diameter.

Since the thread is under pressure, the softened dissimilar polymer exudes into and through interstices existing in the plurality of unsoftened fibers, substantially filling same and forming an internal cast within the matrix of unsoftened fibers upon resolidification. The internal cast of the softened polymer may be continuous or discontinuous and will appear in cross-section in the composite suture as a homogeneous, solid phase throughout the plurality of unsoftened fibers. In most instances, it will be preferred to use an amount of softened polymer sufficient to form upon redistribution throughout the plurality of fibers of the unsoftened synthetic fiber an external cast extending continuously throughout the thread.

Also, where enough of the polymer component softened is present, the liquified polymer exudes through the interstices of the unsoftened fibers and onto the surface of the thread so as to form a coating thereon.

In all instances, however, the internal cast formed within the matrix of unsoftened fibers serves as a tena-

cious "anchor" onto which additional softened synthetic polymer can be secured as by coating, if desired.

Composite sutures prepared by the present invention having coatings of the exuded synthetic polymer component are preferably smoothed, for instance, by passing them through a heated smoothing die. The smoothed composite thread may then be sterilized if desired to form a surgical suture. In many instances, it may be necessary to further coat the smoothed composite with additional similar synthetic polymer as by extrusion or melt coating to seal and further strengthen the composite thread formed. In addition where the thread is in braided form, subsequent coating tends to eliminate any undulating effect that results as a consequence of the braid and provide a flexible, composite polyfilamentous composite suture having a monofilament-like structure exhibiting improved knottability and knot retention. The improvement in knottability and knot retention characteristics is obtained by virtue of the fact that when a knot is "thrown" and tied down, the suture undergoes a marked deformation in the knot due to the "hills and dales" of the underlying thread.

DETAILED DESCRIPTION OF THE INVENTION

By the term "softening" as used herein and the appended claims is meant any operation by which one of the synthetic polymer components of the thread treated but not the other is brought from a solid or highly viscous state to a viscosity causing flow of the synthetic polymer under the prevailing conditions. This "softening" can be achieved by a variety of ways such as by the use of heat, selective solvents, high energy sources such as lasers, etc. Other suitable ways of effecting the softening will readily come to the mind of those of ordinary skill in this art.

In the aspect of the invention wherein the softening is induced by heating, the thread, comprised of a matrix of a plurality of fibers of a first synthetic polymer and a second solid, dissimilar synthetic polymer having a melting point lower than the melting point of said first synthetic polymer is heated at a elevated temperature sufficient to melt and liquify the dissimilar synthetic polymer, to a viscosity permitting flow throughout the matrix.

Similarly, where the "softening" is induced by a solvent, the thread of dissimilar synthetic polymer components is contacted at a temperature and with a solvent capable of solubilizing or softening the second synthetic polymer but not the first at the contact temperature. The contact time will vary depending principally upon the particular synthetic polymer to be softened and the solvent and contact temperature employed. In all instances, however, the contact time will be sufficient to cause one of the synthetic polymer components to flow, that is, to reduce the viscosity of the polymer to where it flows under the external pressure applied according to the invention and through the remaining, or unsoftened synthetic fibers so as to fill the voids or interstices therein. There is thus formed an internal cast throughout the thread which is dried to resolidify the exuded softened polymer component.

The thread softened in accordance with the present invention can assume a variety of structures and the polymer component to be softened can be present during the softening in any desired form such as a film or fiber, or as a coating on the polymer not softened. In one embodiment, for example, the thread is comprised

of lower melting point synthetic polymer fibers in a plied, twisted, braided or commingled construction with synthetic polymer fibers of higher melting point. A preferred form of this embodiment involves heating under tension a thread comprised of a cover of a polyfilamentous synthetic polymer surrounding a core of at least one but preferably a plurality of fibers of a dissimilar synthetic polymer having a lower melting point than the synthetic polymer of said cover.

Alternatively, the thread to be heated pursuant to the present invention can comprise, at least in part, a plurality of synthetic polymer fibers coated with a dissimilar synthetic polymer having a melting point lower than that of the synthetic polymer fiber substrate, which coated fibers are in a plied, twisted, braided, commingled or simply aligned construction.

The proportions of lower melting point synthetic polymer component to higher melting point synthetic polymer component employed in the thread heated in accordance with the invention will vary depending principally upon the particular components selected, whether or not a continuous or discontinuous internal cast is desired and whether or not a composite coated with melted components is the intended product. In all instances, however, the component melted should be present in amounts at least sufficient to provide adequate anchoring sites for additional like synthetic polymer material that may be subsequently applied as a coating to the composite thread formed.

In general, the ratio of higher melting point synthetic polymer material to lower melting point synthetic polymer material in the initial thread required to achieve adequate anchoring sites is at least 0.5:1 on a volume basis. Ratios of melted to unmelted synthetic polymers in excess of 1:10 up to 2:1 are generally required, however, if it is desired to not only fill all the interstices of the thread but to coat the thread as well. Proportions in excess of about 12:1, can create processing difficulties due to thread line non-uniformities.

Heating of the precursor thread of multiple synthetic polymer components to temperatures above the melting point of one of the synthetic components can be conducted in any suitable manner as by passing it through a suitable oven preferably under an inert gas such as nitrogen. As the composite thread passes through the oven, the synthetic component of lower melting point melts and under the applied pressure exudes through the voids present in the plurality of higher melting fibers remaining leaving them substantially filled. Preferably the softened polymer exudes onto the surface under the tension applied.

Any excess melted synthetic polymer can then be trimmed off manually but it is preferred that the thread structure thus formed be passed through a heated die which trims nubs from the thread and otherwise smooths the external surface of the thread. If the thread thus formed is to be coated, it is important to select a die in this operation which provides a precoated yarn that is at least 20-40 microns thinner than the suture class limits in order to leave room for the coating. Again, it is preferred that this operation be conducted under an inert gas such as nitrogen. Stretch may also be applied during the smoothing operation. The thread may be passed through the heating oven and/or smoothing die as many times as is necessary to obtain a smooth, nub-free surface. Advantageously, in smoothing down the nubs not only should excess surface polymer be removed, but some of it should be used to fill the ups and

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downs of the thread's surface in order to obtain a sufficiently smooth undercoat structure. If this is not done, the polymer remaining on the surface follows the contours of the thread and any subsequently applied polymer coating will follow these contours.

The temperature employed in the heating oven will vary depending on the polymer components and the speed at which the thread is passed through the oven. As aforementioned, the temperatures should be raised above the melting point of the polymer of lower melting point to a level at which the polymer melts and reaches a viscosity permitting it to exude through the thread as a gelatinous mass which can then be seen on the surface of the thread when it cools. Excessively high temperatures which then the lower melting polymer to a point where it runs off should be avoided as they tend to exude too much polymer and fail to produce a solid cast structure.

Regardless of the method utilized to induce the required pressure, the actual or optimum pressure applied will vary depending principally upon the particular synthetic polymer components that make up the thread, the softening conditions, the flow viscosity of the softened polymer compound and the nature of the thread construction, i.e. braid, twist, yarn, etc. It is important to note, however, that giving the thread a high level of stretch during the heating operation reduces or eliminates the necessity of applying stretch in any subsequent coating and final sizing stages that may be employed.

The optimum heating temperature employed in a softening operation wherein one of the polymer components is melted will not only depend upon the particular polymer of lower melting point employed but also on the melting point and/or the zero strength temperature of the higher melting polymeric component forming the matrix. In the case of polymers having high crystallinity, the more important consideration is not so much the melting point of the lower melting polymer but rather the temperature at which the polymer reaches a fluidity or viscosity that facilitates exudation. In the case of non-crystalline polymers, on the other hand, only the last criterion applies since non-crystalline polymers do not have a melting point. Usually this temperature is in excess of the melting point of the polymer. For example, to obtain acceptable fluidity with isotactic polypropylene which melts at about 160° C., the polymer should be heated at a temperature within the range of about 180° to 280° C. depending on its molecular weight. Fiber-forming polyethylenes will generally process in the range of about 160° to 275° C. Nylon 66 (polyhexamethylene adipamate) usually will require a heating temperature of about 280° to 295° C. and polyethylene terephthalate a heating temperature of about 270° to 320° C.

Smoothing die temperatures will also be above the melting point of the lower melting synthetic polymer and usually below the melting point of the dissimilar synthetic polymer component. In most instances, the smoothing die temperatures will conform closely to the temperature employed in the heating, i.e. structure formation/precoating stage. Preferably the smoothing die temperature about 5 to 15 degrees below that used in the structure formation/precoating stage.

In a preferred embodiment of the invention, the smooth composite suture structure formed is subjected to coating stage wherein polymer is melt extruded onto the structure. Any of the conventional extrusion apparatuses can be employed for this purpose. The smooth

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composite suture structure is simply fed through the extrusion coating die and coated with additional polymer of the same type as used in the structure formation, i.e. precoating stage. Optionally, a smoothing operation can follow this stage using a heated die as described above.

The extrusion temperatures employed in the coating stage depend upon the polymer added and generally will conform to those employed in the heating operation. It has also been found that when the coating is done with apparatus of the melt flow rheometer type the higher the coating temperature, other conditions being equal the greater the finished suture diameter. This is due to decreased melt viscosity with increased temperatures which results in increased polymer flow under a given applied force. The thickness of the polymer coating can be easily regulated by changing the applied extrusion force. If the coated suture is to be subjected to a final sizing operation this thickness should be 30-40 microns larger than the required final size.

After a coating stage, the coated thread preferably undergoes a final size stage. Ordinarily, a thread leaving the coating stage is thicker than the USP size limits. In order to bring it to USP size requirements, a size or calibration process is carried out. The final sizing in such cases is made by passing the coated suture through the calibration die, preferably a non-split die. In addition to its sizing function the calibration die has additional operations: (a) all possible homogeneities in the coating are eliminated (b) squeezing the coated suture through the hot calibration die results in additional co-melting of the polymer in the sheath with the polymer on the surface of the precoated thread, thus improving the adhesion of the coating to the thread and (c) if for some reason the flow rate of the polymer melt changes at extrusion during the coating stage, it results in increased thickness of the coating. The calibration die will control the final thickness by scraping off excess polymer coating.

The coated suture should contact the walls of the calibration die while still in the molten state, in order to prevent abrasion of cold polymer coating passing through the calibration die. The distance between the outlet of the coating die and the calibration die should be minimal in order to secure a coated suture which is sufficiently rigidified so that when it goes through the calibration die it takes the shape of the die but at the same time it should be soft enough to give a smooth finish. Distances of 5 to 7 cm have been found suitable. On leaving the coating die the coating thickness of the suture should be significantly larger (by 30-40 m) than the inner diameter of the calibration die in order that the space in the capillary part of the die and the entrance to the die will always be filled by the polymer melt. On the other hand, too heavy a coating will cool faster leaving the coating die and will not be heated up rapidly enough to pass through the calibration die. This will disturb the scraping action and will produce breaks in the suture or a rough surface.

When softening of the second synthetic is effected by the use of solvent, the solvent selected will depend, of course, upon the nature of the first component of thread treated since the latter must not soften during the operation. The following are illustrative of solvents generally suitable for use in softening exemplary types of synthetic polymers:

Polyesters—mixtures of halogenated hydrocarbons (e.g. methylene chloride) and halogenated alkanols (e.g. hexafluoroisopropanol).

Aromatic polyamides—strong acids and bases

Nylons—phenols

Polyolefins—aromatic hydrocarbons (e.g. xylene, toluene)

The synthetic/polymer components selected for compositing in accordance with the present invention are without limitation provided they are toxicologically acceptable, fiber- or film-forming polymers, possessing softening points sufficiently distant from each other to permit softening of one without softening or otherwise degrading the other. Thus, the synthetic polymers can be thermoplastic or non-thermoplastic polymer materials illustrative of which are homopolymers and copolymers of a olefins of 1-6 carbons, e.g. polyethylene, polypropylene, polybutene, polyisobutylene, copolymers of ethylene and propylene and the like; polyacrylates such as polymethacrylate, polyethacrylate, and the like; polyamides such as Nylon 66, i.e. poly(hexamethylene adipamide), Nylon 610, i.e. (polyhexamethylene sebacamide), Nylon 6, i.e. polycaprolactam; aromatic polyamides, such as those described in U.S. Pat. Nos. 3,063,966; 3,600,350; 3,671,542 and 3,819,587, all incorporated herein by reference, particularly poly(p-benzamide); poly(p-phenylene terephthalamide); poly(2-chloro-p-phenylene terephthalamide); poly(2,6-dichloro-p-phenylene-2, 6-naphthalamide); poly(p-phenylene-p,p-biphenyldicarboxamide); poly(p, p'-phenylene benzamide and poly(1,5-naphthylene terephthalamide); copoly(p,p'-diaminobenzanilide terephthalamide); polyesters of difunctional carboxylic acids and diols such as polyethylene terephthalate, poly(1,4-cyclohexylene dimethylene terephthalate); polystyrene; poly(acrylonitrile); polyurethane, polyethers, polyvinyls, polypeptides such as polylactides, polyglycolides and copolymers of lactide and glycolide with each other and with other reactive monomers such as those described, for instance, in U.S. Pat. Nos. 3,636,952 and 2,683,136, incorporated by reference herein; and polymers of p-aminobenzoic acid.

Illustrative of suitable composite threads for treatment in accordance with the present invention are set forth in the following Table I:

TABLE I

Composite	Matrix	Extruding Polymer
1	polyethylene terephthalate	isotactic polypropylene
2	Kevlar ⁽¹⁾	polypropylene
3	Kevlar ⁽¹⁾	polyethylene
4	Kevlar ⁽¹⁾	polyethylene terephthalate
5	chain extended polyethylene ⁽²⁾	atactic polypropylene
6	Kevlar ⁽¹⁾	polyglycolic acid
7	Nylon 66	isotactic polypropylene
8	Nylon 66	polyisobutylene
9	polyethylene terephthalate	Nylon 11

⁽¹⁾ Aromatic polyamide product of DuPont Corporation

⁽²⁾ High strength polyolefin yarn having straight pull tenacity of approximately 25-30 g/denier described in Keller A. and Barham, P. J., "High Modulus Fibres", Plastics and Rubber International, Feb. Vol. 6, No. 1 (1981) incorporated herein by reference.

The following examples are included to further illustrate preparation of composite sutures of the invention. In the examples, reference is made to the following brief description of the drawings wherein:

FIG. 1 is a schematic drawing of an apparatus useful in the three stage melting method of the present invention and

FIG. 2 is a schematic drawing in section of a spinneret useful in the extrusion coating of the formed composite suture employed in the apparatus of FIG. 1.

EXAMPLE I

Structure Formation or Precoating Stage

Directing attention to the drawings, using a conventional New England Butt braider machine polyethylene terephthalate (PET) strands of 40 denier are braided around a single core of 265 denier isotactic polypropylene to form a 4/0 raw or precursor thread with 4 ends of 40 denier PET in the cover and 1 end of 165 denier polypropylene in the core. The raw braid, wound around a reel 2, is fed through a guide 4, between nip rollers 5 about a feed roll (Godet) 6, through guide 8 into a heated 10 cm long tubular over inside Spinneret I designated 11 in FIG. 1. The lumen of Spinneret I without polyolefin feed serves this purpose, Heated Zone I in FIG. 1. A roll (Godet) 13 pulls the raw braid through the oven at a stretch ratio (SR) of 1.24. The heating oven is maintained at a temperature of 230° C. Under these conditions all the polypropylene melts and is entirely distributed throughout the braid interstices and onto the surface of the braid. No solid polypropylene core residue remains.

As the braid emerges from Spinneret I, large quantities of excess polypropylene which has melted out and formed nubs on the surface is trimmed off by a smoothing die 12 having an internal diameter (ID) of 0.180 mounted at the outlet of Spinneret I. The braid then continues through a Guide 15 to Spinneret II designated 39 which is an extrusion coating die apparatus shown in detail in FIG. 2.

Coating Stage

The smoothed precoated braid is pulled through Spinneret II by a roll (Godet) 50. Tension is let down on roll 50 so that some overfeed, i.e. a stretch ratio (SR) of approximately 0.9 is applied. Isotactic polypropylene chips are melted in heated reservoir 41 maintained at a temperature of 260° C. and the melt is forced by means of extruding weights 43 applying a force of 0.233 kg to a piston 45 into and through the tubing-type extrusion coating die apparatus 39.

Directing particular attention to FIG. 2, the extruding coating apparatus 39 is comprised of a holder indicated generally as 47 which houses a hollow guide tube 49 and a die holder 50 which retains a die 51. Die 51 has an outlet 52. The guide tube 49 is essentially positioned within the holder 47 so as to provide an annular chamber 53. A Teflon gasket 55 seals one end of the guide tube 49 within the holder while the other end is connected to die 51 and sealed by aluminum gaskets 54, 56 and 58. The guide tube contains an inlet 59 and an outlet 61. Between outlet 61 and outlet 52 of the die 51 is positioned a hollow needle 63. The polypropylene melt from heated reservoir 41 is forced by piston 45 through channel 65, into annular chamber 53 and over needle 63. The impregnated/precoated thread 65 passes consecutively through guide tube 49, hollow needle 59, outlet 52 and is coated with the melt as it emerges from the die 51. The coating die is maintained at a coating temperature of 230° C.

Final Sizing or Calibration Stage

The coated thread is passed to a Spinneret III designated 66 whose design is like that of Spinneret I except that a calibration die 67 (see FIG. 1) having an internal diameter of 0.220 mm is employed so as to provide a finished 4/0 suture. Spinneret III is positioned approximately 5 cm from the outlet of Spinneret II so as to provide a coated thread cooled to a rigidity that allows the coated thread when it enters Spinneret III to take the shape of calibration die 67 but is soft enough to give a smooth finish. The working temperature of Spinneret III is 220° C. Some overfeed (Stretch Ratio, SR approximately 0.9) is applied in the finishing stage as in the coating stage so as to improve the smoothness of the final product.

The finished suture is finally wound around receiving reel 69 and identified in the Table II below as CK suture 4-0.

Sutures of 3-0, 5-0 and 6-0 diameter size were similarly prepared and the mechanical properties of these sutures, identified below as CK sutures 3-0, 5-0 and 6-0 as well CK Suture 4-0 are reported in Table II. Also included for purposes of comparison are the mechanical properties of commercial sutures of like size.

knot values 50-60% higher than CK Sutures of the same size. For PET Braid Suture 4-0 and 5-0 the difference is about 20%.

Gurley Stiffness

By comparing all materials having the same 3-0 size (samples 1-5, all of them monofilaments) it is seen that the CK Suture 3-0 has the lowest Gurley Stiffness (G.S.). Size 3-0 polypropylene monofilaments (Prolene from ethicon and PP from Thiokol) and nylon monofilament (from Deknatel) have G.S. 2.5-3 times higher than that of similarly sized CK Suture. PET 3-0 monofilament has the highest G.S. — 6.3 times higher than that of the CK Suture.

When comparing G.S. of size 4-0 materials (samples 6-10) it can be seen that the G.S. of Prolene 4-0 is still remarkably higher (by 68%) than that of the KC Suture but, on the other hand, the G.S. of PET 4-0 multifilament suture from Deknatel is two times lower than that of CK Suture 4-0. Such a result is not surprising when comparing the stiffness of multifilament with monofilament yarns.

In the size 5-0 the G.S. of CK Suture is 39% lower than that of Prolene, but 3.9 times higher than that of PET 5-0 multifilament.

TABLE II

No.	Type of Suture	Knot-pull Tensile Strength, F_{knot} (g)		Percent Elongation (%)	Knot Security		Gurley Stiffness G.S. (mg)
		Required by USP*	Measured		K_{ave}	$n_{1/5} - 1/5$	
1	CK Suture 3-0	1200	1436	15.0	2	—	8.2
2	Prolene 3-0 (from Ethicon)	"	1504	58.3	3	$n_{1/5} = 5$	19.8
3	PP Yellow Monofil. 3-0 (from Thiokol)	"	1430	39.4	3	$n_{1/5} = 5$	24.9
4	Nylon White Monofil. 3-0 (from Deknatel)	"	1434	50.4	4	$n_{1/5} = 5$	22.8
5	PET Monofil. 3-0	"	2430	76.1	3	$n_{1/5} = 5$	52.0
6	CK Suture 4-0	750	930	12.8	2	—	5.9
7	Prolene 4-0 (from Ethicon)	"	946	56.7	3	$n_{1/5} = 5$	9.9
8	PP Blue Monofil. 4-0	"	841	29.1	3	$n_{1/5} = 5$	14.4
9	Nylon White Monofil. 4-0 (from Deknatel)	"	950	47.8	4	$n_{1/5} = 5$	12.4
10	PET Green Braid Suture 4-0	"	1146	16.5	4	$n_{1/5} = 1$	3.0
11	CK Suture 5-0	500	649	14.2	2	—	2.2
12	Prolene 5-0 (from Ethicon)	"	646	44.9	3	$n_{1/5} = 5$	3.1
13	PP Blue Monofil. 5-0	"	532	31.5	3	$n_{1/5} = 3$	5.9
14	Nylon White Monofil. 5-0 (from Deknatel)	"	577	51.0	4	$n_{1/5} = 5$	5.4
15	PET Green Braid Suture 5-0 (from Deknatel)	"	770	25.2	4	$n_{1/5} = 1$	0.6
16	Suture 6-0	250	318	11.0	2	—	0.4
17	Prolene 6-0 (from Ethicon)	"	270	50.0	3	$n_{1/5} = 4$	0.6
18	PP Blue Monofil. 6-0	"	192	29.9	3	$n_{1/5} = 5$	1.1
19	PET Monofil. 6-0	"	485	37.0	3	$n_{1/5} = 5$	3.3

*The limits on F_{knot} apply to non-sterile sutures.

RESULTS

Knot-Pull Tensile Strength

Sizes 3-0, 4-0 and 5-0 CK Sutures have the same F knot as Prolene and Nylon Monofilaments (the differences being within the limits of 3% except for Nylon 5-0 which is 12% weaker than CK Suture 5-0). It should be noted that the values of 5-0 sutures are 20-30% higher than required by U.S.P. In size 6-0 the F knot of the CK Suture is 18% higher than that of Prolene. PP monofilament (blue) is remarkably weaker than the CK Suture (the difference increases from 11% in size 4-0 up to 66% in size 6-0).

PET sutures have F knot values higher than CK Sutures. PET Monofilaments of 3-0 and 6-0 have F

It may be safely stated that, when comparing CK Suture with other sutures of the same size, the G.S. of CK Sutures is remarkably lower than that of Prolene, PP, PET and Nylon monofilaments. This difference is particularly high when comparing with PET monofilaments of the same size. On the other hand, the G.S. of CK Sutures is remarkably higher than that of PET multifilament sutures. This results from the structure of CK Sutures.

Elongation

The P.E. of CK Sutures of all sizes varies from 11% to 15%. The P.E. of other monofilament sutures is much higher, for example: P.E. of Prolene in all sizes varies

from 43% to 58%; of PP monofilament from 29% to 39%; of NNylon monofilament from 41% to 51%; and of PET monofilament from 37% to 76%. Only P.E. of PET monofilament suture 4-0 (16.5%) is close to the desired variance.

Knotability

Knotability results show that the CK Suture has the lowest stiffness and elongation when compared with other monofilament sutures. It can, therefore, be stated on the basis of these two quantitative parameters, that the knotability of the CK Suture is better than that of any other monofilament suture.

Knot Security

It may be seen from the Tables that all investigated materials can be divided into 3 groups with corresponding k_{sec} 2, 3 and 4. CK Sutures belong to the group with k_{sec} 2. All Prolene sutures, PP monofilaments and PET monofilaments belong to the second group with k_{sec} 3. PET braids and nylon monofilaments belong to the third group with k_{sec} 4. It means that with CK Sutures, a secure knot can be tied using only two throws Square Knot. All other investigated materials need at least one additional throw for secure knot formation and nylon monofilaments and PET braids need even two additional throws.

Micronscopic examination (250X) of a cross-section of the finished suture shows virtually no dead spaces present. The finished suture is free of stripping and cracking and possesses the smoothness of a monofilament.

In commercial production, needles may be attached to one end of the composite sutures of the invention and the sutures may be packed in sterile containers. Inasmuch as the sutures are stable for long periods of time without a conditioning fluid, the sutures may be dry packed in glass tubes or plastic envelopes. Conditioning fluid may be used to assure maintenance of sterility or as a lubricating medium for the needle. Eyeless needles are preferred since they cause less tissue damage. Conveniently, the composite sutures of the present invention are formed at convenient lengths, attached to eyeless needle, wound on reels if desired, and placed in containers such as plastic envelopes. The sutures may then be sterilized with ethylene oxide or other conventional gaseous sterilizing agents in accordance with known practices. Alternatively, the sutures may be sealed in the envelopes and then sterilized by using heat and radiation including x-rays, gamma rays, electrons, neutrons, etc.

EXAMPLES II-IX

Example I is repeated using the following synthetic materials as the matrix and core, i.e. lower melting point component and conducting the heating in Heating Zones I and II as indicated.

Ex- am- ple	Matrix	Core	Spinneret I, °C.	Spinnerette II & III, °C.
II	Kevlar ⁽¹⁾	isotactic polypropylene	220	220
III	Kevlar ⁽¹⁾	polyethylene	225	220
IV	Kevlar ⁽¹⁾	polyethylene terephthalate	265	265
V	chain extended polyethylene ⁽²⁾	isotactic polypropylene	70	45
VI	Kevlar ⁽¹⁾	polyglycolic	238	230

-continued

Ex- am- ple	Matrix	Core	Heating Zone I, °C.	Heating Zone II, °C.
VII	Nylon 66	isotactic polypropylene	230	222
VIII	Nylon 66	polyisobutylene	300	190
IX	polyethylene terephthalate	Nylon 11	237	237

(1) } See Table I, supra
(2) }

It is claimed:

1. A method of preparing a surgical suture comprising forming a thread having interstices therein, comprised of a plurality of fibers of a first synthetic polymer, said thread further comprising second synthetic polymer in intimate association with and present along the length of at least one of said plurality of fibers, said second synthetic polymer having a lower melting point than said first synthetic polymer, heating the thread to a temperature sufficient to liquify the second synthetic polymer but not the first synthetic polymer to cause flow thereof, placing the thread under tension during said melting to compress the thread and redistribute the liquified second polymer throughout the plurality of fibers of said first synthetic polymer so as to substantially fill the interstices of said thread, said liquified polymer being present during said redistribution in an amount sufficient to exude through the interstices of the unmelted fibers and onto the surface of the thread to form a coating thereon and to form an internal cast extending throughout said thread, said internal cast forming an anchor onto which additional second synthetic polymer can be secured, if desired, and sterilizing the resulting thread to form a surgical suture.

2. A method according to claim 1 wherein the second synthetic polymer is in fiber form.

3. A method according to claim 1 wherein the first synthetic polymer is aromatic polyamide.

4. A method according to claim 3 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

5. A method according to claim 3 wherein the aromatic polyamide is poly(1,4-benzamide).

6. A method according to claim 1 wherein the first synthetic polymer is chain extended, polyethylene having a straight pull tenacity of about 30 to 50 grams/denier.

7. A method according to claim 3 wherein the first synthetic polymer is polyester.

8. A method according to claim 7 wherein the polyester is polyethylene terephthalate.

9. A method according to claim 1 wherein the second synthetic polymer is polyolefin.

10. A method according to claim 9 wherein the polyolefin is polyethylene.

11. A method according to claim 9 wherein the polyolefin is polypropylene.

12. A method according to claim 1 wherein said coating is subjected to smoothing.

13. A method according to claim 12 wherein said smoothing is effected by passing the composite after said heating through a heated smoothing die.

14. A method according to claim 1 wherein the composite formed is coated with the same synthetic polymer as said second synthetic polymer.

15. A method according to claim 14 wherein the coated composite is subjected to smoothing.

16. A method according to claim 15 wherein said smoothing is effected by passing the composite after said heating through a heated smoothing die.

17. A method according to claim 1 wherein the second synthetic polymer comprises at least one fiber.

18. A method according to claim 17 wherein the second synthetic polymer is polyolefin.

19. A method according to claim 18 wherein the polyolefin is polypropylene.

20. A method according to claim 19 wherein the polyolefin is polypropylene.

21. A method according to claim 1 wherein the first synthetic polymer is a polyamide terephthalate.

22. A method according to claim 21 wherein the polyamide is aromatic polyamide.

23. A method according to claim 22 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

24. A method according to claim 22 wherein the aromatic polyamide is poly(1,4-benzamide).

25. A method according to claim 21 wherein the polyamide is poly(hexamethylene adipamide).

26. A method according to claim 21 wherein the polyamide is polycaprolactam.

27. A method according to claim 21 wherein the polyamide is poly(hexamethylene sebacamide).

28. A method according to claim 20 wherein the polyamide is poly(w-aminoundecanoic acid).

29. A method according to claim 1 wherein the first synthetic polymer is polyester.

30. A method according to claim 29 wherein the polyester is polyethylene terephthalate.

31. A method according to claim 1 wherein the first synthetic polymer is extended polyethylene having a straight pull tenacity of about 30 to 50 grams/denier.

32. A method according to claim 1 wherein the first synthetic polymer is polypropylene, the second synthetic polymer is polyethylene terephthalate and the softening achieved by heating the composite to a temperature of about 180° to 280° C.

33. A method according to claim 1 wherein the first synthetic polymer is polyethylene terephthalate the second synthetic polymer is polyethylene and the softening is achieved by treating to a temperature of about 160° to 275° C.

* * * * *

June 8, 1965

A. GLICK

3,187,752

NON-ABSORBABLE SILICONE COATED SUTURES AND METHOD OF MAKING

Filed April 27, 1962

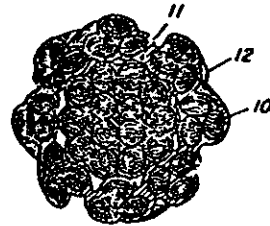


Fig. 1

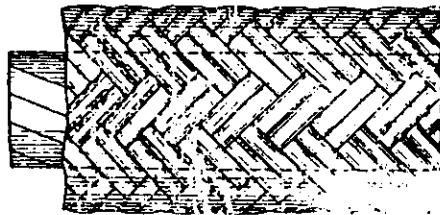


Fig. 2

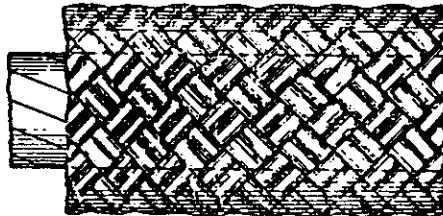


Fig. 3

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DePuy Mitek, Inc. v. Arthrex, Inc.
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3,187,752
NON-ABSORBABLE SILICONE A COATED SUTURES
AND METHOD OF MAKING

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Filed Apr. 27, 1962, Ser. No. 194,604
26 Claims. (Cl. 122—335.5)

This application is a continuation-in-part of application Serial Number 767,502, filed October 16, 1958 and now abandoned.

This invention relates to a non-absorbable densely constructed suture built up of a plurality of filaments having a serum-proof, moisture-resistant coating on the surface of the individual filaments, which coating contains a silicone resin.

As used in this specification the term "suture" is intended to include both sutures, and are used for the sewing of tissues, and ligatures are used for tying off blood vessels, etc. Different portions of one strand may be used for both purposes in the same operation depending upon the needs of the surgeon at the particular moment.

In surgical practice; and for present purposes, this includes both human and animal surgery, two classes of sutures are commonly used. One is the absorbable suture which is absorbed by the tissues and accordingly loses its identity, such sutures usually being of catgut, etc.; and the other form is a non-absorbable suture which in most instances is permitted to remain as such permanently in the tissues, but which is sometimes removed from the tissues at an appropriate phase of the healing process. Such non-absorbable sutures must be strong and should maintain their strength and integrity for prolonged periods while in contact with body tissues and fluids. It is desirable that such sutures be inert, causing a minimum of tissue irritation, and that the diffusion of fluids through the suture by capillarity be at a minimum.

It has been customary to use silk sutures built up as by braiding, weaving, twisting or spinning, hereafter called coordinate configuration, of from a plurality of individual silk filaments. Synthetic polymers may be used instead of natural silk. These filaments present a construction in which there are fine interspaces which by capillary action cause fluids to travel along these length of the suture. This may permit migration of pathogenic organisms.

Accordingly, such sutures have been coated with waxes, such as beeswax, or beeswax mixed with ethyl cellulose, which material reduces the capillarity of the suture and improves the handling characteristics of the suture.

There is some evidence that under some conditions these waxes cause granuloma formation, and have other undesirable side effects.

Additionally the coating material should be inert to all body fluids and heat stable to permit heat sterilization of the suture. It is desirable that the coating be economical and readily applied.

In addition to the physiological properties of inertness the characteristics of handling and of strength of a suture are extremely important. It is desirable that a suture be sufficiently stiff that it can be easily handled and yet readily formable to a new position. After being bent to a new position, it should maintain this new set position. Many fibrous materials have a plastic "memory," and after being bent to a new position slowly on standing tend to go back to their former shape. A suture should not have plastic "memory" but should when once set maintain that new position.

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Additionally the suture should be easy to tie into a knot and should be resistant to knot-slippage under tension and the knot should remain secure and not slip or unravel itself on standing. Additionally, a suture should have what is known as "throwability." That is, the surgeon should be able to pick up the suture and throw it into a new position, which position is then retained. It is desirable at times to place a suture in a given location or throw it in a given direction with the knowledge that the suture will stay there until positively moved.

In the past a great deal of the handling characteristics have been imparted to a limp suture by the coating material. Beeswax or beeswax mixed with ethyl cellulose used as a coating is responsible for the desirable handling characteristics.

If some other coating material is used with the same filament construction, the sutures may not have satisfactory handling characteristics.

It has now been found that by braiding a suture with a tighter and more dense construction using fewer plies, i.e. cross-overs per inch, and by dry stretching the braided filaments, a suture can be formed which has inherently stiffer qualities and improved handleability.

Silk is the usual material used for non-absorbable sutures. Synthetic filaments such as nylon, polypropylene, "Orlon," polyacrylonitrile, "Dacron," a stretched oriented polyester of ethylene glycol and terephthalic acid, etc., or cotton, or linen are sometimes used. Occasionally such materials as stainless steel or monel metal are used. All such materials can be advantageously coated with polymeric silicones, in accordance with this invention, and are braided or spun or formed more tightly for coating with silicones than with conventional coating materials.

Polymeric silicones are applied to this dense suture; such polymeric silicones readily coat the individual filaments increasing the resistance to aqueous fluids without reducing capillarity. Furthermore, such silicones applied as a coating are heat stable. In at least some instances the coating may be applied in a partially polymerized state and the silicone further polymerized in position on the suture. Fortunately and fortuitously, polymerization catalysts are decomposed by heat sterilization procedures or heat curing so that even if toxic catalysts are used as a component of the silicone containing, the final product is completely inert.

The particular silicone resin themselves are not a part of this invention and standard commercial resins may be used. It is not necessary that the material be applied as a liquid, as some of these silicone resin forming materials, such as the General Electric "Dellumet," are volatile and may be applied in the gaseous phase. These materials are among the volatile silicone compounds such as alkyl silicone halides. A material such as dimethyl silicone dichloride is comparatively volatile and may be applied either direct or by allowing it in an ethereal solution thereof to evaporate and the vapor contact the suture material.

Frequently, it is more convenient to use a liquid preparation. Such preparations are solvent dispersions of "silicone resins," that is partially polymerized products which will polymerize to a silicone film. For purposes of convenience it is normally easier to purchase the material under trade names rather than making it, or obtaining it to a performance specification. Materials which are sold commercially such as the Dow-Corning silicone "TDC 803" or "DC 804" or General Electric's "9980" give highly satisfactory and useful films. To those skilled in the art of silicone compounding it is comparatively simple to select a heat-curable or potentially heat-curable silicone resin, which either from its inherent characteristics, or

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the addition of a polymerizing catalyst, will set up or cure. As a final check to insure the complete removal of all halide to silicone linkages, ammonia fumes may be used. Usually sufficient moisture is present to insure the hydrolysis of the halogen, but ammonia fumes insure a neutral product. If desired, silicone containing resins may be used in which the silicone atoms are linked through nitrogen, from ammonia, rather than through oxygen as in the silicones, such resins at times being referred to as silamines.

Methods for preparation of silicone resins are well known. Patent No. 2,306,222 to W. I. Patnode, "Method of Rendering Materials Water Repellent," discloses the use of a vapor of an alkyl silicone halide for making glass vapor-proof. The same types of materials as therein described may be used to water-proof and treat sutures. The patent to Safford, No. 2,424,853, and the patent to Tanis, No. 2,408,822, additionally describe siliceous halides and their conversion to resins. There are several methods of preparing such silicone resins, among others are the reaction of Grignard type reagents with a silicone tetrachloride. From the standpoint of costs silicone tetrachloride is normally used and the Grignard may be either alkyl or aryl or a mixture thereof. The amounts of alkyl and aryl groups used affect the brittleness and rate of cure of the resin formed. Normally the product of the reaction of the Grignard reagent with silicone tetrachloride is allowed to react with moisture, allowed to partially polymerize, and the partially polymerized materials are dissolved in a suitable solvent whereby additional polymerization is either inhibited or substantially slowed down. The higher the ratio of lower alkyls, the more rapid the materials will cure and the more brittle will be the film. The more highly branched the chains formed in the resin, which are necessarily formed by the polymerization of the silicone types containing more halide atoms per silicone molecule, the more brittle and polymerized are the resins.

The organo-silicones sometimes referred to as organopolysiloxanes, more particularly the hydrocarbon substituted polysiloxanes are particularly suitable for suture coating. The patent to Wright et al., No. 2,339,477, entitled "Polysiloxane Resins" gives considerable information of this type of resin. Certain of the resins which are described in the patent to Hyde, No. 2,386,466, "Insulated Conductor and Insulation Therefor," if diluted with a solvent may be used in accordance with the instant invention. The patent to Hyde, No. 2,371,050, "Organosilicone Polymers and Method of Making Them," describes certain additional methods of preparing such resins. It is not necessary that the resins be prepared from halogen containing compounds as, for example, methods such as set forth by Strain et al. in Patent No. 2,394,642, "Silicic Acid Esters," describes a different form of silicone containing resin. The patent to Her, No. 2,395,350, "Modified Alkyd Resins," describes still further modifications of silicone containing resins in which the silicone linkages are different than those classified as organopolysiloxanes.

It is not intended that a treatise be here included on the production of such resins, as such resins are the invention of others and are adequately described in the patent literature, as well as elsewhere. The texts "Introduction to the Chemistry of the Silicones," Eugene G. Rochow, John Wiley & Sons, Inc., New York, 1946, and "Silicones and Their Uses," Rob Roy McGregor, McGraw-Hill Book Company, New York, 1954, give many useful details.

A pamphlet "Silicones in Medicine and Surgery," Rob Roy McGregor, Dow-Corning Corporation, 1957, discloses some of the silicones which may be used, and other medical usages for such silicones.

The silicone acts as a protective layer on the surface of the filaments, and prevents dyes or the surface characteristics of the filaments, such as silk, from interacting

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with body fluids. In neural surgery, suture materials frequently deleteriously affect regeneration of nerve fibers. Silicone coated silk is the first material known to have been successfully used in suturing nerve fibers which permits the regeneration of the nerves in the spinal column.

Usually silk is braided loose enough for a beeswax coating to impregnate the silk, reduce capillarity, and impart desirable handling qualities. The new silicone coating may not inherently have enough body to give the desired handling qualities. Rather than use a more highly polymerized silicone resin, which is stiffer, it is preferred to use a denser silk construction, with more silk filaments in a given cross-section. This gives a greater strength, and a thinner silicone coating gives a proper inertness to the suture and at the same time prevents capillarity.

One standard test for capillarity is to boil two 3 to 4 inch lengths of the suture in distilled water in a glass container for three successive 20-minute periods, changing the water each time. After the third boiling, the test sutures are allowed to stand for at least 8 hours in an atmosphere having a relative humidity of $65\% \pm 2\%$ at a temperature of $21^\circ \pm 1^\circ$ C. The segment of suture is tied to a piece of white silk thread with a square knot, the ends cut close, and suspended by the white silk thread so that the suture dips into a 0.5% aqueous solution of methylene blue, with the knot $\frac{1}{8}$ -inch above the dye solution. After standing for 24 hours, the white silk is inspected for evidence of dye carried up the suture by capillary action. If the white silk is free from dye color, the suture is non-capillary, and passes the test. Both of the duplicate samples should pass.

Sutures of this invention pass this test for capillarity. Sutures which pass this test are non-capillary in tissues of man and animals.

For preventing slippage at knots in the suture, a coating forming a hardened, but flexible silicone film is preferred, using a silicone having a higher ratio of aryl groups. For instance, a polysiloxane having from about 72% to 67% methyl substituents and from 28% to 33% phenyl groups cures to a non-slipping finish that gives excellent knot retention. Usually the suture breaks before the knot slips. Also such polysiloxanes are sufficiently adhesive that spun sutures of silk or other filaments do not unravel, or "broom," and can be threaded into needles.

The silk construction itself rather than the coating can be used to give the handling qualities.

Whereas the number of ends, and total denier, varies with size, it is desirable that a maximum size, and strength be obtained within the overall limits of suture diameter. For the standard United States Pharmacopoeia sizes (United States Pharmacopoeia Convention, Inc., Distributed by Mack Publishing Co., Easton, Penn., elsewhere abbreviated U.S.P.) this is:

U.S.P. size	U.S.P. diameter, inches, max.	Picks per inch	Denier of raw silk used
4-0	0.004	40	112
5-0	0.005	47	125
6-0	0.006	53	137
7-0	0.007	60	150
8-0	0.008	67	162
9-0	0.009	73	175

The picks per inch are the number of threads, running in one direction, per lineal inch of suture.

The silk is braided using a smaller number of picks than conventional, and with a larger core size. The braided silk is washed to degum, then dyed, if desired, in skeins in accordance with conventional practice. The silk is dried, and then dry stretched from about 6% to about 11% of its length. This stretching tightens the braid, and gives a more dense, more handleable silk. At least some of the stretching may be accomplished while the silk is wet.

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After stretching the silk suture is passed through a solvent bath containing the polymeric silicone. Such solvents as xylene, toluene, benzene, gasoline, or other non-toxic volatile hydrocarbon solvents may be used. In addition to the silicone, beeswax, ethyl cellulose or a low molecular weight polyethylene may be dissolved and used as part of the coating. For the silicone rubbers, a catalyst is usually used to accelerate the curing rate. The standard organic peroxides, of which benzoyl peroxide is the most frequently used, are suitable catalysts, 2% to 20% by weight of the polymer gives good results. The heat which sets the resin decomposes residual peroxides to give non-toxic products. For the hardened, flexible films, having a higher percentage of phenyl groups, heat alone can cure the silicone. Organo metallic driers such as zinc octoate, or iron stearate accelerates the cure. Non-toxic salts of metals with fatty acids are effective.

A 2% to 50% solids bath gives a satisfactory coating. A 5% to 30% solids concentration in the bath results in easier operating control. A 20% concentration is usually preferred. While an adequate pick up with a single coating bath is obtainable, more uniform distribution and coating can be obtained by using two or more baths, with heat curing between coatings. A cure temperature of at least 150° C. for 30 seconds gives a cure, although longer times at lower temperatures, or a longer cure with less catalysts, etc. in accordance with standard practice in the silicone art may be used.

A total weight of coat of 2% to 20% by weight of the fiber gives good characteristics. This percentage is called the pick up.

The sutures are shown in the attached drawings:

FIGURE 1 is a cross-section of a silicone coated suture.

FIGURE 2 shows a portion of an eight carrier ca a 16 capacity carrier braider formed braid.

FIGURE 3 shows a portion of a sixteen carrier braid.

EXAMPLE 1

A silk suture is braided, using 8 carriers, on a sixteen carrier braider, with 3 ends of 13 to 15 denier silk per carrier, and a core of 3 ends of 13 to 15 denier silk, and 40 picks per inch, giving the skipped braid of FIGURE 2. The raw silk used has a total of about 378 denier. (The denier is the weight in grams of 9000 meters of the strand.) The braided suture is washed to degum, then dried, while looped in skeins. The dry silk is stretched 9% of its length, which gives improved stiffness; and increases the density.

A silicone rubber sold as "Silastic 9711" by Dow-Corning is milled into sheets of about 1/4-inch thick, and thereto while milling additionally is added 8.46% by weight of the rubber of a silicone fluid containing 50% by weight benzoyl peroxide (Lupercos ASF). After milling for an additional 5 minutes, the sheets are cut into small pieces and soaked overnight in xylene. The swollen silicone is stirred to a cream-like consistency, then diluted to 20% solids, and stirred until uniform.

The braided silk is immersed in a trough of the silicone solution at room temperature, then wiped over a piece of white felt. The coated silk is passed through a three stage heating tunnel, so that the silk is heated for one minute each at 100° C., 125° C., and 150° C. The silk is spooled after air cooling.

This coating procedure is repeated. In the double coating, the silk is found to have picked up 15% by weight of the silicone coating.

The finished suture gauges 0.0077 inch in diameter and is a 4-0 suture.

A conventional braiding of a 4-0 suture gives about 60 to 70 picks per inch, and uses 8 carriers with 2 ends of 21-22 denier each, and no core. Such a silk suture has a total denier of about 336, and if coated with beeswax in accordance with conventional practice gauges .0085 inch.

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Other characteristics for comparison are:

	Silk With New Silicone	Silk With Old Silicone
Picks per inch.....	40	60
Gauge.....		
Raw.....	.0076	.0081
Sterilized.....	.0077	.0083
Straight pull strength.....	2.77	2.00
Knot pull strength.....	2.94	1.80
Flexibility to bend, 180°.....	.137	.100
Strength-inches self support:		
Horizontal (sterile).....	2.04	4.75
Vertical (sterile).....	4.00	5.15
Apparent density as braided.....	1.137	0.927

The increase in strength after sterilization both straight and over a knot shows the new silicone construction to have marked advantages.

The suture is sterilized either by conventional autoclaving procedures, or by ethylene oxide gas, in accordance with commercial practice in the industry.

The individual silk filaments of the braid are shown at 10, the filaments of the core are shown at 11, and the suture has a silicone coating 12. FIGURE 2 shows the construction of a 000 suture, otherwise the same as above.

EXAMPLE 2

The coating of the suture of Example 1 is repeated using a 15% solids solution of a dimethyl silicone polymer of the general formula $((CH_3)_2SiO)_n$ with 5% by weight of the polymer of benzoyl peroxide as catalyst. After two coatings, a readily handleable suture is obtained.

EXAMPLE 3

A multi-filament 4-0 sized silk suture braided as in Example 1 is washed and dyed black in accordance with conventional procedures. The suture is then dry stretched. An alkyl polysiloxane sold by General Electric as "TS-188" is diluted with toluene to form a 10% silicone solids solution. The silk suture is immersed in this solution of the silicone resin at 50° C., then drawn through a curing tunnel at a temperature of 130° C., and of such length as to heat the silk suture for two minutes. The suture may be heated longer, so as to sterilize the suture at this time after which it is sterily packed and handled until used by the surgeon; or after the two-minute heating, the suture may be reeled and packaged using clean but not sterile techniques and finally sterilized by dry heat after packaging and prior to sale, or just prior to use by the surgeon.

EXAMPLE 4

A 4-0 silk suture braided, washed, and dried as described in Example 1 is immersed in a 10% solids solution of the polymerizing silicone resin commercially known as Dow-Corning 804. This resin is a comparatively short chain silicone resin containing both phenyl and methyl substituents on the silicone atoms. The silk suture is immersed in the solution of the silicone, the excess wiped off with a piece of felt, and the coated suture cured by passing through a curing tunnel in which the coated silk is heated to 130° C. for three minutes. The silk suture may be sterilized by heating, as desired, but before use. About 12% by weight of the silk of the silicone remains in the coating.

EXAMPLE 5

The silicone rubber sold as Dow-Corning "Silastic 9711" is milled with 4.2% of benzoyl peroxide for five minutes, cut into small pieces, covered with xylene, and soaked overnight. The swollen material is stirred with additional xylene to obtain a 20% solids concentration. Braided silk prepared as described in Example 1 is passed through the silicone in xylene, wiped with a piece of white

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felt, then cured for one minute each at temperatures of 100° C., 125° C., and 150° C. The silk picks up about 10% by weight of silicone solids. The silk suture is heat sterilized before use. The thus prepared suture is used in operations to suture wounds after surgery. The suture is found to be satisfactory and causes a minimum of tissue irritation and deleterious after-effects.

A pigment or dyestuff may be added to the coating solution if desired. Such coloration of the coating is particularly useful for synthetic filaments which are difficult to color.

EXAMPLE 6

A multi-filament size 3-0 braided polyester suture was coated in two passes with a silicone rubber bath containing 17% silicone solids dispersed in xylene. The coating and curing procedure was as described in Example 5. The suture picked up 2.9% by weight of silicone solids. The polyester suture was non-capillary.

EXAMPLE 7

A multi-filament 2-0 silk suture was braided using 16 carriers each containing 3 end 15 denier silk; a core of 14 ends 20-22 denier silk; a pick count of 50; and a total denier of 966. The construction is of the type shown in FIGURE 3. The braided suture was coated with a methyl phenyl polysiloxane which contains about 72% methyl groups and 28% phenyl groups. The coating bath contained 35% silicone solids in xylol. The excess coating was wiped off with a piece of sponge rubber and the coating was cured for one minute each at temperatures of 100° C., 125° C., and 150° C. The silk picked up 7% by weight of silicone solids for one coat. A second coat under the same conditions yielded a total pick up of 12%. The silk at both coating levels was non-capillary, had good bond and showed good resistance to brooming. Surgeon's knots tied in the silk broke before slipping.

EXAMPLE 8

A multi-filament spun, or twisted, 3-0 silk suture was coated with a methyl-phenyl polysiloxane, processed and cured as in Example 7. The spun and twisted silk had a silicone pick up that ranged from 7% for a single coat to 12% for a double coat. The silk did not broom or bush and the filaments were bonded together, so that a needle could be readily threaded.

EXAMPLE 9

A multi-filament size 3-0 braided nylon suture was coated in two passes in a silicone rubber bath containing 17% silicone solids dispersed in xylene. The coating and curing procedure was that described in Example 5. The nylon suture picked up 4.5% by weight of silicone solids and was non-capillary. Good results were obtained when used in surgery.

EXAMPLE 10

A multi-filament braided 3-0 suture was coated with a bath containing 30% solids of a silicone resin commercially sold as Dow-Corning 804. This resin is a comparatively short chain silicone resin containing both phenyl and methyl substituents on the silicone atoms. Added to this bath was a plasticizer amounting to 20% of the weight of the silicone solids. The silk was immersed in this bath, the excess silicone wiped off with sponge rubber and the silicone was cured in a tunnel for one minute each at temperatures of 100° C., 125° C., and 150° C. The silk for a single coat had a silicone pick up of 7% of the weight of the silk. Silk with two coats had a pick up of 12% silicone resin. Silk coated in this resin bath and the added plasticizer had good hand, was non-capillary and did not broom. Plasticizers used were alkyl aryl phosphates, phthalates, sebacates, citrates, epoxies and polymeric dimethyl siloxanes.

The polysiloxanes containing larger proportions of aryl groups require larger amounts of plasticizers. The

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pick up can be readily varied by the pressure on the wipers. A slower cure at a lower temperature gives a good coating. A more rapid cure is generally preferred, as the cure most conveniently takes place in a tunnel, and if a slower cure is used the tunnel must be longer for a given production rate and hence is more expensive.

I claim:

1. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 6-0; picks per inch 40; denier of raw silk used 112; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments.

2. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 5-0; picks per inch 40; denier of raw silk used 252; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments.

3. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 4-0; picks per inch 40; denier of raw silk used 378; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments.

4. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 3-0; picks per inch 40; denier of raw silk used 630; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments.

5. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 00; picks per inch 50; denier of raw silk used 966; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments.

6. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 0; picks per inch 50; denier of raw silk used 1560; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments.

7. The method of making surgical sutures comprising braiding a plurality of filaments of silk into a hard dense core, washing the gum from the braided silk, drying the braided silk, dry stretching the braided silk about 6 to 11% of its length, immersing the braided silk in a xylene solution of a polymerizable silicone, wiping the braided silk suture, whereby there is a silicone pick up of about

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10% to 20% by weight, and drying and polymerizing said silicone.

8. The method of making surgical sutures comprising braiding a plurality of filaments of silk into a hard dense core, washing the gum from the braided silk, drying the braided silk, dry stretching the braided silk about 6 to 11% of its length, immersing the braided silk in a solution of a polymerizable silicone rubber containing a catalyst, wiping the braided silk suture, whereby there is a silicone pick up of about 10% to 20% by weight, and drying and polymerizing said silicone by heat, of at least about 150° C. for at least about 30 seconds, thereby also decomposing the catalyst.

9. The method of making surgical sutures comprising braiding a plurality of filaments of silk into a hard dense core, washing the gum from the braided silk, drying the braided silk, dry stretching the braided silk about 6 to 11% of its length, immersing the braided silk in non-toxic volatile hydrocarbon solvent solution of a polymerizable silicone rubber containing a catalyst, wiping the braided silk suture, drying and polymerizing said silicone, re-immersing in said solution, re-wiping the suture, whereby there is a total silicone pick up of about 10% to 20% by weight, and drying and polymerizing said silicone by heat, of at least about 150° C. for at least about 30 seconds, thereby also decomposing the catalyst.

10. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 6-0; picks per inch 40; denier of raw silk used 112; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said coating weighing from 10% to 20% of the weight of the silk filaments.

11. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 5-0; picks per inch 40; denier of raw silk used 252; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said coating weighing from 10% to 20% of the weight of the silk filaments.

12. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 4-0; picks per inch 40; denier of raw silk used 378; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said coating weighing from 10% to 20% of the weight of the silk filaments.

13. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 3-0; picks per inch 40; denier of raw silk used 630; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said coating weighing from 10% to 20% of the weight of the silk filaments.

14. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 00; picks per inch 50; denier of raw silk used 964; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said coating weighing from 10% to 20% of the weight of the silk filaments.

15. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction:

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U.S.P. size 0; picks per inch 50; denier of raw silk used 14560; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said coating weighing from 10% to 20% of the weight of the silk filaments.

16. A surgical suture comprising a plurality of individual filaments in coordinate configuration, the filaments being banded together to hold the filaments in a unitary strand, and hence non-brooming, having a coating on each filament of a non-toxic, physiologically inert, polymeric silicone, whereby the suture is non-capillary and is inert towards living tissue, the weight of said silicone being from 10% to 20% of the weight of the uncoated filaments.

17. A surgical suture comprising a plurality of individual filaments selected from the group consisting of silk, nylon, polypropylene and stretched oriented polyester, the external filaments being in braided configuration, having a tight braid, and low pick count, with high density, thereby imparting surgically handleable characteristics to the uncoated suture, and a coating on each filament of a non-toxic physiologically inert polymeric silicone, whereby the suture is non-capillary and is inert towards living tissue, the weight of said silicone being from 10% to 20% of the weight of the uncoated filaments.

18. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, and low pick count, with high density, thereby imparting surgically handleable characteristics to the uncoated suture, and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, whereby the suture is non-capillary and is inert towards living tissue, the weight of said silicone being from 10% to 20% of the weight of these uncoated filaments.

19. A surgical suture comprising a plurality of individual silk filaments in coordinate configuration, each filament having thereon a coating of a polymethyl-polyphenyl siloxane, at least the final polymerization being *in situ*, the weight of said silicone being from 10% to 20% of the weight of the uncoated filaments, whereby these suture is non-capillary and is inert towards living tissue, and the siloxane coating causes the filaments to adhere to each other, and thereby be free from brooming, and which suture, when tied in a surgeon's knot, breaks rather than slips, on pulling in tension.

20. The method of making surgical sutures comprising braiding a plurality of filaments of silk into a hard dense core, washing the gum from the braided silk, drying the braided silk, dry stretching the braided silk about 6 to 11% of its length, immersing the braided silk in a solution of a polymerizable silicone, wiping the braided silk suture, whereby there is a silicone pick up of an amount sufficient to render the finished suture non-capillary and not more than 20% of the weight of the uncoated filaments, and drying and polymerizing said silicone.

21. The method of making surgical sutures comprising braiding a plurality of filaments of silk into a hard dense core, washing the gum from the braided silk, drying the braided silk, dry stretching the braided silk about 6 to 11% of its length, immersing the braided silk in a solution of a polymerizable silicone rubber containing a catalyst, wiping the braided silk suture, whereby there is a silicone pick up of an amount sufficient to render the finished suture non-capillary and not more than 20% of the weight of the uncoated filaments, and drying and polymerizing said silicone by heat, of at least about 150° C. for at least about 30 seconds, thereby also decomposing the catalyst.

22. The method of making surgical sutures comprising braiding a plurality of filaments of silk into a hard dense core, washing the gum from the braided silk, drying the braided silk, dry stretching the braided silk about 5 to 11% of its length, immersing the braided silk in non-toxic

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volatile hydrocarbon solvent solution of a polymerizable silicone rubber containing a catalyst, wiping the braided silk suture, drying and polymerizing said silicone, re-immersing in said solution, re-wiping the suture, whereby there is a total silicone pick up of an amount sufficient to render the finished suture non-capillary and not more than 20% of the weight of the uncoated filaments, and drying and polymerizing said silicone by heat, of at least about 150° C. for at least about 30 seconds, thereby also decomposing the catalyst.

23. A surgical suture comprising a plurality of individual filaments in coordinate configuration, the filaments being bonded together to hold the filaments in a unitary strand, and hence non-brooming, having a coating on each filament of a non-toxic, physiologically inert, polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments, and the suture is inert towards living tissue.

24. A surgical suture comprising a plurality of individual filaments selected from the group consisting of silk, nylon, polypropylene and stretched oriented polyester, the external filaments being in braided configuration, having a tight braid, and low pick count, with high density, thereby imparting surgically handleable characteristics to the uncoated suture, and a coating on each filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments, and the suture is inert towards living tissue.

25. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, and low pick

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count, with high density, thereby imparting surgically handleable characteristics to the uncoated suture, and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments, and the suture is inert towards living tissue.

26. A surgical suture comprising a plurality of individual silk filaments in coordinate configuration, each filament having thereon a coating of a polymethyl-polysiloxane, at least the final polymerization being in situ, the weight of said silicone being an amount sufficient to render the finished suture non-capillary and not more than 20% of the weight of the uncoated filaments, and said suture is inert towards living tissue, and the siloxane coating causes the filaments to adhere to each other, and thereby be free from brooming, and which suture when tied in a surgeon's knot, breaks rather than slips, on pulling in tension.

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2,588,365	3/52	Dennett	
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RICHARD A. GAUDET, *Primary Examiner.*

JORDAN FRANKLIN, *Examiner.*

United States Patent ⁽¹⁹⁾

Perciaccante et al.

(11) 4,047,533
(45) Sept. 13, 1977

[54] **ABSORBABLE SURGICAL SUTURES
COATED WITH
POLYOXYETHYLENE-POLYOXYPROPY-
LENE COPOLYMER LUBRICANT**

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[73] Assignee: American Cyanamid Company,
Stamford, Conn.

[21] Appl. No.: 724,804

[22] Filed: Sept. 20, 1976

[51] Int. Cl.² A61L 17/00

[52] U.S. Cl. 128/335.5; 128/1 R;
428/375

[58] Field of Search 128/1, 335.5; 428/275

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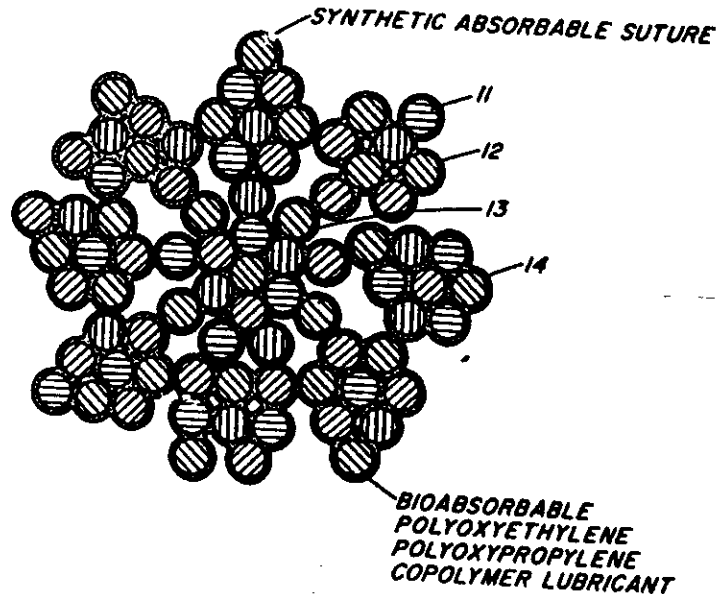
3,061,470 10/1962 Kuemmerer 428/375 X
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Primary Examiner—Leland A. Sebastian
Attorney, Agent, or Firm—Charles F. Costello, Jr.

[57] ABSTRACT

The handling characteristics, including particularly the knot run-down, of synthetic absorbable surgical sutures and tissue drag characteristics are improved by a coating of a lubricating film of a bioabsorbable copolymer having polyoxyethylene blocks and polyoxypropylene blocks, and which bioabsorbable copolymer has a molecular weight such that it is pasty to solid at 25° C.

23 Claims, 2 Drawing Figures



U.S. Patent

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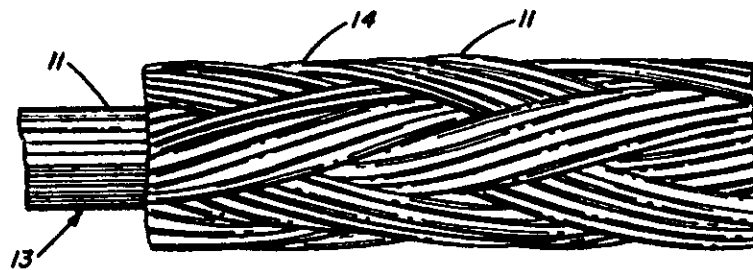
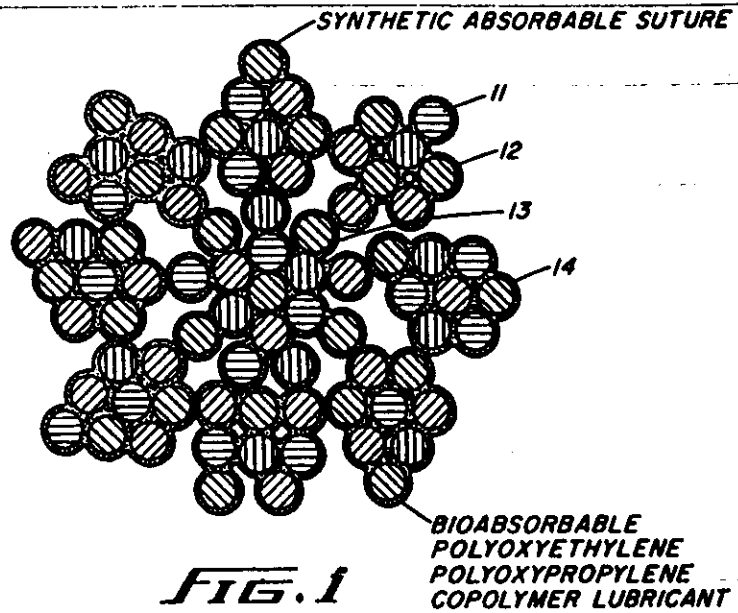


FIG. 2

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ABSORBABLE SURGICAL SUTURES COATED WITH POLYOXYETHYLENE-POLYOXYPROPYLENE COPOLYMER LUBRICANT

BACKGROUND OF THE INVENTION

The handling characteristics of surgical sutures encompass many factors, some of which factors are at least in part inconsistent or seemingly inconsistent. There is a constant effort to improve the handling characteristics. Among the more important of the handling characteristics are those associated with knot run-down. In many surgical procedures it is necessary that a knot be tied in a suture when the knot is deep inside a surgical or natural opening. For instance, a dental surgeon may need to tie a knot inside a patient's mouth. An intravaginal hysterectomy requires suturing in restricted quarters. One technique frequently used is to tie a square knot that can be run-down from an exterior location where the knot is first tied to lie against tissue with a desired degree of tightness. The knot is snugged down so that it is holding with a degree of firmness chosen by the surgeon for a particular situation and then additional throws are tied down against the first throws of the square knot. In some instances, the first throw is a double twist followed by a single throw to form a surgeons knot, with additional throws to form additional square knots on top as needed. As contrasted with the ease of placement, is the necessity of knot security. Each though it is desired that it be easy to tie a knot, it is mandatory that the knot hold without slipping for an acceptable length of time. With buried absorbable sutures, of course, the suture including the knot is eventually absorbed, and the knot need only hold until the tissue is adequately regenerated. This can be merely a few hours for certain types of skin incisions, up to requirements of the order of 15 to 28 days for many types of internal knots. If strength for a longer time or permanent reinforcement is needed, non-absorbable sutures may be used.

Some suture materials are so smooth that a knot runs down very readily and frequently becomes readily untied. Other sutures are of materials in which the knot tends to "lock-up" or refuse to run-down so that it is difficult to snug-down the throws against the tissue and only a few throws are needed, and security is not a problem. Knots in constantly moving tissue, such as adjacent to the heart, have a much greater chance of becoming untied than knots in quiescent tissue such as knots holding together a wound inside a plaster cast.

The problem of improving suture performance under varied conditions has been the subject of much research over a prolonged period.

PRIOR ART

U.S. Pat. No. 1,234,031 — Jan. 22, 1918, Davis, SUTURE AND METHOD OF MAKING THE SAME, shows a braided collagen suture immersed in collagen or glue to cause close adhesion of the braid, to fill up the interstices and provide a smooth uniform coating.

U.S. Pat. No. 2,576,576 — Nov. 27, 1951, Cresswell and Johnstone, LUBRICATED THREAD, shows a lubricated multifilament collagen thread using as a lubricating film a phosphatide such as lecithin. The lecithin should be applied at the time of coagulation or regeneration of collagen as effective lubrication is not

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obtained if the lubricant is incorporated by adding to a finished thread.

U.S. Pat. No. 2,734,506 — Feb. 14, 1956 - Nichols et al. SILK SUTURES AND LIGATURES shows using poly(alkyl methacrylate as a coating for silk sutures, and a hot coating die system.

U.S. Pat. No. 3,187,752 — June 8, 1956 — Glick, NON-ABSORBABLE SILICONE COATED SUTURES AND METHOD OF MAKING, shows silk or other non-absorbable synthetic filaments such as nylon, cotton or linen coated with a silicone which gives a more inert suture and reduces capillarity.

U.S. Pat. No. 3,209,589 — Oct. 5, 1965 — Schlatter, YARN FRICTION MEASURING INSTRUMENT, describes a machine for measuring the friction of a yarn sliding over itself and describes the variation of friction with speed, and the "slip-stick" variety at slow speeds.

U.S. Pat. No. 3,297,033 — Jan. 10, 1967 - Schmitt and Pollstina, SURGICAL SUTURES, shows synthetic surgical sutures of polyglycolic acid and discloses that the surfaces of the fiber can be coated with a silicone, beeswax, or the like to modify the handling or the absorption rate.

U.S. Pat. No. 3,390,681 — July 2, 1968, Kurtz, POLYESTER SUTURE HAVING IMPROVED KNOTTING CHARACTERISTICS, shows improving the knotting characteristics of a polyester such as one formed from a dicarboxylic acid and a diol (Dacron) by depositing on the fibers a polytetrafluoroethylene (Teflon). This patent discloses many of the problems in suture knots, and is hereby incorporated by this reference hereto. This patent also shows the accepted practice of classing "ligatures" under "sutures" for patent disclosure purposes.

U.S. Pat. No. 3,565,077 — Feb. 23, 1971, Glick, DENSIFIED ABSORBABLE POLYGLYCOLIC ACID SUTURE BRAID, AND METHOD FOR PREPARING SAME, shows a suture construction using polyglycolic acid filaments with a compacted structure and a reduced void fraction.

U.S. Pat. No. 3,815,315, June 11, 1974, Glick, ETHYLENE OXIDE STERILIZATION OF MOISTURE SENSITIVE SURGICAL ELEMENTS shows the desirability of maintaining surgical elements of polymers subject to the hydrolytic degradation to non-toxic, tissue-compatible, absorbable components, such as polyglycolic acid sutures, in a desiccated condition in an air tight container impervious to moisture vapor. Suitable desiccating cycles and foil containers to give product which are storage stable for years are disclosed.

U.S. Pat. No. 3,867,190 — Feb. 18, 1975, Schmitt and Epstein, REDUCING CAPILLARITY OF POLYGLYCOLIC ACID SUTURES, shows the coating of polyglycolic acid surgical sutures with a copolymer of from 15-85% glycolic acid with 85-15% lactic acid which coating fills the interstices of a multi-filament polyglycolic acid suture. Example 10 discloses the coating as minimizing capillarity, and improving run-down. Thicker coatings increase stiffness. This patent has 38 references to earlier prior art on sutures and methods of making them, and related fields and is incorporated herein by this reference thereto. A divisional of said 3,867,190 is Ser. No. 489,004, July 16, 1974, REDUCING CAPILLARITY OF POLYGLYCOLIC ACID SUTURES, now U.S. Pat. No. 3,982,543 dated Sept. 28, 1976.

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U.S. Pat. No. 3,896,814 — July 29, 1975 — Vivien and Schwartz, COLLAGEN BASED THREADS, shows a collagen or catgut thread which is flexibilized by having therein water and a hygroscopic agent such as a glycerol or a glycol or a low molecular weight (up to 400 m.w.) liquid polyalkylene oxide, and which may additionally be coated with a lipoid or a silicone for surface lubricity.

U.S. Pat. No. 3,942,532 — Mar. 9, 1976 — Hunter and Thompson — BRAIDED SUTURE, discloses an adaptation of an INSTRON Universal Testing Instrument using an oscillographic recorder, to use a single throw between two suture strands to measure surface roughness, as an indication of the ease of sliding a single throw knot down the suture into place, there called "tie-down performance". A coating of 0.4 percent to 7 percent of the suture weight of an aliphatic polyester such as a condensate of adipic acid and 1,4-butanediol having a molecular weight of about 2,000-3,000 is recommended.

U.S. Ser. No. 691,749, filed June 1, 1976 — Casey and Epstein — NORMALLY-SOLID BIOABSORBABLE, HYDROLYZABLE, POLYMERIC REACTION PRODUCT, discloses the use of transesterification product of poly(1,4-propylene diglycolate) and polyglycolic acid and other trans-esterification products of polyglycolic acid and a polyester of diglycolic acid and an unhindered glycol to coat sutures to improve knot run-down and other suture characteristics.

The coating, coloring and conditioning of surgical sutures with polymeric materials in general is well-known. Silicones, wax, polytetrafluoroethylene, and other polymers have been used. Specific coating materials with unique advantages to give improved sutures are constantly being sought.

SUMMARY OF THE INVENTION

It has now been found that the knot run-down characteristics, handleability, tie-down performance and tissue drag characteristics of braided, twisted or covered multifilament synthetic absorbable sutures may be improved by coating with a lubricating biologically absorbable copolymer having polyoxyethylene blocks and polyoxypropylene blocks.

Absorbable polyglycolic acid sutures are described in U.S. Pat. No. 3,297,033, supra. Other synthetic absorbable sutures which absorb in living tissue may be coated with improved results. At present absorbable sutures meeting with market acceptance are those in which the degradation or absorption in tissue results from the hydrolytic degradation of glycolic acid ester linkages. Such materials are presently being sold under the trademarks DEXON® and VICRYL®. The present invention may be used with other synthetic absorbable surgical sutures, described in the prior art, and as they are developed. With synthetic absorbable sutures the problem of a coating to improve knot run-down characteristics is made more difficult by the requirement that the coating must be non-toxic and absorbable.

Absorbable or bioabsorbable as applied to the coating, refers to a coating which by hydrolytic or enzymatic degradation, or by its inherent characteristic, has such molecular weight and solubility properties that it is absorbed from the surface of the suture and is eliminated by the subject either unchanged or in hydrolyzed or degraded form. The exact mechanism of the disposition of the coating in mammalian tissue is not critical

to the understanding of the present invention, as long as the coating is non-toxic.

It is also found that the lubricant coating not only aids in the knot run-down characteristics but increases the smoothness and flexibility of the sutures so that they may be more easily drawn through the skin and other tissues during placement of the suture. This reduction in friction is called reduced tissue drag.

Another unexpected and unobvious advantage of the present lubricant coating in that the lubricant copolymers are absorbed from the suture within a few days. The coating that aids in friction reduction in tissue drag and lubricates in knot placement also causes the knot to slip more readily. When the lubricant is comparatively rapidly absorbed in living mammalian tissue, the resistance of the knot to slippage or untying due to tissue movement is soon increased. As the wound heals the knot security actually improves, up to the time that the synthetic absorbable suture loses strength preliminary to absorption.

The absorbable coating is one or more of a group of compounds having blocks of polyoxyethylene and blocks of polyoxypropylene in their structure. For simplicity and ease of description these compounds are taught, drawn and treated as if there were merely two or three blocks in the chain. However, it is to be understood that non-significant quantities of polyoxypropylene may be present in the polyoxyethylene block and minor quantities of polyoxyethylene may be present in the polyoxypropylene block. From the methods of manufacture it would appear that there may be and probably are such minor admixtures present in the chain. The commercially available grades are acceptable and found to have a low and acceptable degree of toxicity.

The present lubricants may be indicated as having the formula:



where one of R_1 and R_2 is methyl and the other hydrogen, and n and m are sufficiently large that the compound is pasty to solid at 25° C., R is the residue of a relatively low molecular weight reactive hydrogen compound having from 2 to about 6 reactive hydrogen atoms and having not over 6 carbon atoms in said compound, and c is the number of reactive hydrogens on the compound forming R . Those compounds which are at least pasty at 25° C. are preferred because they adhere better to the synthetic absorbable polyfilamentary suture. There is not a sharp cut off, but in general as the materials become more pasty or solid, their effectiveness improves.

The lubricant compounds and methods of manufacture are described at length in certain prior art. The Pluronic in general are described in U.S. Pat. No. 2,674,619, Apr. 6, 1954, POLYOXYALKYLENE COMPOUNDS, L.G. Lundsted. These are referred to as a cogenetic mixture of conjugated polyoxypropylene-polyoxyethylene compounds and are further described therein.

Certain nitrogen containing polyoxyethylene detergent compositions which are here useful as lubricants are described in U.S. Pat. No. 2,979,528, Apr. 11, 1961, NITROGEN-CONTAINING POLYOXYALKYLENE DETERGENT COMPOSITIONS, L.G. Lundsted. Column 4, lines 44-58 of this patent disclose

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that the oxypropylene chains may have a small amount of ethylene-oxide therein and vice versa. Because of the sources of ethylene oxide and propylene oxide, usually from petroleum fractions, it is to be expected that in commercial practice complete rectification to chemically pure compounds is not obtained. Fortunately the commercial grade may be used on absorbable sutures with excellent results. Said 2,979,528 also points out that as polymers, all molecular species are far from identical—some chains are shorter, some are longer, but on the average the materials are as indicated and it is the physical properties of the lubricants, not the molecular weight spread of the components, which are important.

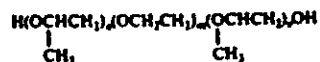
U.S. Pat. No. 3,036,118, May 22, 1962, MIXTURES OF NOVEL CONJUGATED POLYOXYETHYLENE-POLYOXYPROPYLENE COMPOUNDS, D. R. Jackson and L. G. Lundsted, has much disclosure on the addition of polyoxyethylene groups and polyoxypropylene groups to reactive hydrogen compounds having from 2 to 6 reactive hydrogen atoms and not over 6 carbon atoms per molecule. Among other such compounds are listed the group consisting of aliphatic polyhydric alcohols, alkylamines, alkylene polyamines, cyclicamines, amides, and polycarboxylic acids, oxyethylene groups and oxypropylene groups. The reactive hydrogen compound serves as a chain initiator and can be present in such a small proportion that it has minor significance in its own right and serves mainly as a foundation on which the predominantly polyoxyethylene or polyoxypropylene blocks may be added in the chosen order. Whereas Patent 3,036,118 claims primarily the Reverse Pluronics in which the polyoxyethylene chains are attached to the nucleus or initiating reactive hydrogen compounds, in the present invention either the Reverse Pluronic with the polyoxyethylene in the center or the regular Pluronics with the polyoxypropylene in the center or the Tetratics with nitrogen in the center may be used for lubricant purposes.

Because the chemistry is previously known, and to avoid unnecessarily extending the length of the present disclosure, the disclosures of each of these three patents is herein hereby incorporated by this reference thereto.

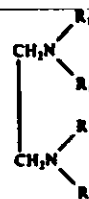
These lubricating bioabsorbable copolymers are often classed as surface active agents as the polyoxyethylene blocks are predominantly hydrophilic and the polyoxypropylene blocks are predominantly hydrophobic. The materials have been sold by the Wyandotte Chemical Company under the trademark of PLURONICS for the formula:



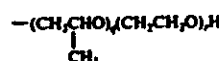
where x, y and z are whole numbers. REVERSE PLURONICS for the formula:



where a, m and o are whole numbers and TETRATICS for the formula:



where R₁ is



where q and r are whole numbers.

For the present purposes as synthetic absorbable suture lubricants, the values of x, y, z, a, m, o, q and r are such that the lubricants are pasty to solid at 25° C.

The pastes are opaque semi-solids with melting points above room temperature—preferably above about 40° C.

Those classed as Pluronics are particularly useful for the present invention.

The physical characteristics of these lubricant compounds are affected by their total molecular weight and by the percentage of polyoxyethylene in the molecule. References are made to the commercially available compounds for purposes of convenience. Those which are liquid normally have an L as a primary designator, those which are pasty have a P and those which are solid have an F. For the Pluronics, the first number indicates the typical molecular weight of the polyoxypropylene hydrophobic portion with a number 3 being about 950; 4 being about 1200; 5 being about 1450; 6 about 1750; 7 about 2050; 8 about 2250; 9 about 2750; 10 about 3250; 11 about 3625 and 12 about 4000. The second digit indicates the approximate percentage of the polyoxyethylene hydrophilic units in the total molecular, in units of 10. Thus for example, the formulations of certain commercially available products is approximately that shown in Table I.

As all compositions are mixtures, all values are approximate, and values are subject to some rounding.

Additional data is given in The Journal of the American Medical Association, volume 217, pages 469 to 470 (1971) where the new nonproprietary name of POLOXAMER is established for these compositions as direct food additives.

TABLE I

PLURONIC	Average Molecular Weight	M.W. of each Polyoxyethylene Block	Units of each a and z	% Polyoxyethylene	M.W. of Polyoxypropylene Block	Units of y	M.P. °C.
F-38	3000	2000	46	80	930	16	45
F-48	8350	1300	75	80	1,750	30	52
F-77	6600	2300	52	70	2,050	35	48
P-35	4600	1200	27	90	2,250	39	40
F-37	7700	2700	62	70	2,250	39	49
F-44	10800	4300	97	80	2,250	39	54
F-98	13500	5400	122	80	2,750	47	55
F-108	14400	5600	128	80	3,150	54	57

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TABLE I-continued

F-127	12500	4300	98	75	3,900	67	56
REVERSE PLURONIC			M.W. polyethylene units of m block		M.W. polyoxy- propylene block		Units of n and O
10R8	1,000	2000	45	65%	363	9	46
17R8	4,330	2600	39	60%	870	15	33
25R8	9,000	3250	74	57%	1,290	22	56

Average		Approximate Molecular Weight of In-	Approximate % Polyox-	Molecular Approximate Weight of In-	Approximate	Average Approximate length of chains per block	
Molecular		dividual Polyox-	ethylene	dividual Polyox-	Polyoxypropylene	Units of r	Units of q
Weight		ethylene Block		ethylene Block			
TETRONIC							
707		2312	74	673	26	52.5	11
908		5588	85	925	15	127	15.9
1107		2438	67	1173	33	55.4	20.2
1307		3213	69	1423	31	73	24.3
1508		5063	75	1673	25	115	28.5

In general, the Pluronics with a molecular weight range of from about 4,750 to 16,250 are waxy solids. The polyoxypropylene portion has a molecular weight of 950 to 4,000 and the polyoxyethylene content of about 60-80%.

The pastes in general have a total molecular weight ranging from 3,500 to 5,700 with a polyoxypropylene molecular weight range of 1,750 to 6,500 and polyoxyethylene content of 30 to 50%. The transitions from wax to paste to liquid are not sharp.

COATING

The synthetic absorbable suture is conveniently coated by several conventional procedures including:

Melt Coating

The uncoated suture is placed in a split die whose orifice corresponds to diameter specifications for the particular size suture to be coated. The die is then clamped in a heating block and the polyoxyethylene-polyoxypropylene lubricant bioabsorbable copolymer placed in the die. The die is raised to a temperature about 20° C. above the melting point of said copolymer and after the copolymer has melted, the suture to be coated is slowly pulled downward through the molten material in the die and collected on a take-up spool. The spool is mounted directly below the die a sufficient distance to allow solidification of the coating. A cooling tunnel or a blast of cooling air may be used to increase production speeds. Nichols et al. 2,734,506, supra, describes one useful apparatus for coating.

Solution Coating

The polyoxyethylene-polyoxypropylene lubricant bioabsorbable copolymer is dissolved in chloroform. About twice the percentage by weight is used for coating solution as is desired on the final sutures. A feed loop such as a loop of wire or a ceramic is threaded with the uncoated suture, after which the feed loop is then submerged in the solution and the suture is passed down through the feed loop. It may be passed through a die whose diameter is such that after drying a suture will have the desired diameter. The suture is pulled slowly through the solution and at least partially dried in a drying tunnel. The drying is finished after the suture is wound on a spool. Because variations in equipment, speed, and temperature affect the pick-up of the lubricant bioabsorbable polymer, the concentration in the coating is adjusted based on a preliminary run or experience.

During the following the application of the coating to the synthetic absorbable sutures, contact of the filaments with moisture, or water vapor is minimized. The

final coated suture is thoroughly desiccated before packaging in a moisture proof container, such as a metal foil envelope, for long term storage stability. U.S. Pat. No. 3,814,315 supra, discloses methods of dry packaging and sterilizing, and is hereby incorporated by this reference thereto.

Other coating techniques which are well known in the coating of polyfilamentary strands may be used. The techniques used for insulating wire may be adapted for large scale suture manufacture. The above are merely two of the more convenient and well known methods for coating. Details are later illustrated in examples.

Toxicity

The low toxicity of the polyoxyethylene-polyoxypropylene compounds of the present invention are shown in such U.S. Pat. Nos. as 3,450,502 which describes the use of a copolymer having a total molecular weight of about 8,750 in isotonic solutions used as a priming agent in a heart-lung apparatus. In sutures even if a maximum of around 25-30% by weight of the suture of copolymer is used, only a very small amount is placed in the subject.

The low toxicity is shown in the following table.

TABLE II

TOXICITY			
Pieronic No.	Total Molecular Weight	Physical Characteristic	LD 50 (gm/kg) in Mice
F-38	3000	wax	> 5
F-77	6600	wax	4.3
F-87	7700	wax	1.75
F-68	8350	wax	> 5
F-88	10800	wax	> 5
F-127	12500	wax	2.25
F-98	13500	wax	> 5
F-106	14400	wax	1.25
P-45	3400	paste	0.83
P-84	4200	paste	0.4
P-83	4600	paste	0.53
P-94	4600	paste	0.6
P-101	4950	paste	1.4
P-104	5850	paste	0.75
P-123	5750	paste	2.7
P-105	6500	paste	3

The polyoxyethylene-polyoxypropylene compositions used as the lubricant bioabsorbable copolymers have been used in food products; and have been the subject of studies as to their elimination from a mammalian body. In general, they are eliminated in the urine fairly rapidly, and within 48 hours nearly all have been eliminated from the blood stream.

If some of the lubricant bioabsorbable copolymer is trapped in braid pores of a suture, the rate of diffusion into the blood stream may be reduced and hence the

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time for elimination somewhat increased. The molecular weight is small enough that the lubricant bioabsorbable copolymers may be eliminated unchanged, although some degradation may occur before elimination. The important thing is that the lubricant bioabsorbable copolymer has no deleterious effect upon healing tissues adjacent to the sutures, and being removed from the surface of the suture by absorption by the body, knot security is improved. As soon as suture placement is completed, the knot run down and tissue drag reduction function is complete, and as the lubricant bioabsorbable copolymer is removed from the suture, knot security improves.

Definitions in the suture and textile trades are sometimes ambiguous or confused. As herein used:

A "filament" is a single, long, thin flexible structure of a non-absorbable or absorbable material. It may be continuous or staple.

"Staple" is used to designate a group of shorter filaments which are usually twisted together to form a longer continuous thread.

An absorbable filament is one which is absorbed, that is digested or dissolved, in living mammalian tissue.

A "thread" is a plurality of filaments, either continuous or staple, twisted together.

A "strand" is a plurality of filaments or threads twisted, plaited, braided, or laid parallel to form a unit for further construction into a fabric, or used per se, or a monofilament of such size as to be woven or used independently.

The term "suture" is used to include the term "ligature" as technically a suture is used with a needle whereas the ligature is merely used to tie without being placed by a needle.

A finished suture has a needle attached and is sterile and ready for use in surgery. For purposes of convenience in nomenclature, the term "suture" is frequently used to refer to the same strand before it is coated and before it is packaged and sterilized. Context indicates whether it is the sterile suture ready for use, or the suture in a manufacturing step which is referred to.

The strand of the suture is used as the basis for weight in determining the quantity of material that is placed on the synthetic absorbable polymer strand in forming the absorbable surgical suture.

The quantity of the lubricating bioabsorbable copolymer is from about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer based on the weight of the uncoated strand forming the suture. It is not necessary that the coating be continuous as a discontinuous coating on the surface aids in reducing friction and chatter. A larger quantity may be present if the lubricating bioabsorbable copolymer penetrates inside the strand, with the various filaments themselves being partially or totally covered.

The wide range of coating weight permits adaptation of the present sutures to many varied uses. Because the strand to be coated to form the suture may have considerable variation in surface roughness, due to the mechanical structure, i.e. braid or twist, etc. as well as being made from filaments which are less than 2 denier per filament to more than 6 denier per filament, with the finer filament sizes giving a smoother surface; and because the filaments may be stretched after the suture is manufactured or in heat treatment, the surface roughness basically can vary. The smoother surfaces require less of the lubricating bioabsorbable copolymer for analogous degrees of slippage.

The various surgical techniques used interact with the desired degree of lubrication. For any given type of knot, a larger quantity of lubricant which for a particular technique increases the ease of run-down, also increases the ease of the knot running back or slipping, called knot security. For some surgical procedures it is highly desirable that the knot be very free in running down, even though the knot slips more readily.

A surgeon in tying knots is confronted with the interaction between the method of tying the knot and the ease of slipping. If a suture is comparatively well lubricated, the surgeon can use a square knot, which is run down readily; with additional squared throws for knot security. On the other hand, if the suture is less well lubricated, the surgeon can use a double half-hitch or some other type of knot which moves more readily to run the knot down to position, after which these double half hitch can be pulled to square the knot, or additional throws can be thrown down against the knot to give adequate knot security. Thus the surgeon can either adapt his knot technique to a particular suture, or can get sutures whose surface lubricity is best adapted to the technique which the surgeon desires to use. Generally, there is an adaptation of each to the other. The surgeon attempts to get a suture whose characteristics are those which he prefers, and then adapts his knot tying techniques to the sutures that he has at the time. Some surgeons make very successful knots with stainless steel wire using a knotting technique that is adapted to such a wire which has very poor run-down. Others prefer a much more readily run-down well-lubricated suture.

Additionally the location of use has influences. Sometimes a suture in passing through tissue picks up tissue fluids. The suture may be coated with tissue fluids which are either fresh or partly dry at the time the knot is tied. In some surgical techniques it is necessary to preplace the sutures, and tie the suture after the coating of tissue fluids on the suture has a chance to become at least partially dried.

Because the ease of knot run-down and knot security are somewhat opposite, it is necessary for the surgeon to use additional throws or such knots as will hold under the particular conditions of a selected surgical procedure. By changing the quantity of the lubricant bioabsorbable copolymer, the run-down can be modified to suit a using surgeons preference.

The time of use of the knots can be quite varied. Some surgeons use a suture to ligate bleeders in a wound with a retention requirement of 30 minutes or less. Such knots can be removed as the surgical procedure is complete, and before wound closure. Others leave the absorbable knots in the tissue even though there is no likelihood that a bleeder would reopen. For such usage, a suture which retains strength for 30 minutes is adequate. For wound closure and some other uses, it is desired that the synthetic absorbable suture maintain strength for at least 15 days to 4 weeks.

Because the present lubricating bioabsorbable copolymer is removed from the suture in living tissue, as the lubricant is removed the knot security increases and after 48 hours more or less, knot security is greatly improved.

The examples following should show the effects of certain different coating and quantities under certain conditions.

The requirements of surgery are extremely varied, and various coating weights permit adaptation of synthetic absorbable sutures to different conditions.

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In general, if the surgeon desires a better lubricated suture, a larger quantity of the lubricating bioabsorbable copolymer is used and conversely if the surgeon is willing to accept slightly reduced knot run-down and tissue drag characteristics in favor of greater knot security, the coating level is reduced in favor of this particular compromise.

Usually from 2 percent to 8 percent of the lubricant bioabsorbable copolymer gives a useful range of compromise between the ease of knot run-down and knot security.

A usage of about 5 percent by weight of Pluronic F-68 is a preferred compromise between the knot run-down and knot security requirements for 2 to 6 denier per filament braided sutures of polyglycolic acid.

In the Drawings:

FIG. 1 is a cross-section of a synthetic absorbable suture having on the surface thereof a bioabsorbable polyoxyethylene polyoxypropylene copolymer lubricant.

FIG. 2 is a drawing of a suture showing the parallel filaments in the core and the braided sheath. The lubricant coating appears on the surface.

The drawings are diagrammatic and representative. The filaments 11 of the synthetic bioabsorbable suture are at best some what jumbled in actual configuration but are illustrated as patterned in a somewhat idealized style. The coating 12 of the lubricant bioabsorbable polyoxyethylene-polyoxypropylene copolymer is shown much exaggerated. At a level of from 0.1 to 25 percent, the coating would be so thin as to merely be represented by a blurred line if to accurate scale.

In FIG. 2 the core 13 of the braided suture consists of parallel filaments and the sheath 14 consists of a plurality of filaments, typically braided in configuration. The type of braid shown is representative and diagrammatic. The visibility and appearance of the coating varies depending upon the observational technique used to inspect the suture.

The coating 12 in part may bridge the gap between the individual filaments in the finished suture. Depending upon the quantity of coating used, the bridging may be more or less complete but complete filling is not necessary. If the coating level is increased, knot run-down continues to be improved, but knot security is compromised.

EXAMPLE 1

Run Down and Chatter Test

A set of 2/0 USP XIX (diameter 0.339 mm, maximum) polyglycolic acid sutures braided from a 2 denier per filament extrusion, was coated with 7 levels of Pluronic F-68 and a blank, that is no coating, then subjected to a square knot run-down test.

In this test, the suture is tied with a square knot around a cylinder with a 4 inch periphery. The loop thus formed is slipped off the cylinder and placed in the testing machine jaws. The knot is subjected to running-down by pulling on the original free ends in a testing machine which records the pull on a chart as the knot travels down the suture. There is some chatter or variation in knot run-down tension as the knot travels down the suture. This is graphically plotted. Out of a set of runs with various coating levels, the fraction is indicated in which the maximum force for the knot run-down is within the separate ranges given in the table. All of the knots for coated sutures ran down the full length of the suture without breaking. The knot break-

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ing strength of the suture braid was in a range of 7 to 8 pounds. For uncoated braid, the knot locked up and the suture broke in 9 out of 10 tests.

TABLE III

Knot Run-Down on 2/0 Polyglycolic Acid Sutures With Pluronic F-68 Lubricant	
Coating Level	Fraction of trials where maximum resistance was:
	0-1 1-2 2-3 3-4 4-5 5-6 6-7 lbs.
(percent)	
0.0	broke before run-down in 9 out of 10
1.9	2/10 2/10 4/10 2/10
2.8	2/10 3/10 2/10 3/10
3.9	1/10 1/10 4/10 2/10 3/10
5.0	3/10 2/10 2/10 2/10 1/10
6.2	2/10 3/10 2/10 3/10
7.4	1/11 1/11 4/11 3/11
8.0	3/10 2/10 3/10
The maximum force for run-down decreases steadily with increasing level. Lower coating levels on a different batch of braid showed	
0.51%	1/10 2/10 2/10 3/10 2/10
1.09%	3/10 1/10 3/10 1/10
1.53%	3/10 1/10 1/10 1/10 1/10 1/10

For these coatings, the braid was run through a solution of Pluronic F-68 at a concentration of about twice the percentage of coating on the suture in chloroform.

With other braid constructions and other sizes, the relative ease of knot run-down may be greater or less for the same quantity of coating, or conversely the quantity of the coating may be adjusted to give the desired knot run-down values.

The quantity of the Pluronic in the solvent may be varied, and solvents other than chloroform may be used.

Other organic solvents such as methyl alcohol, ethyl alcohol, isopropyl alcohol, methylene chloride, warm xylene (about 60° C.), tetrahydrofuran, acetone, dimethylformamide, dimethyl sulfoxide, mixtures thereof, and other similar solvents for the lubricant may be used for coating. Flowing the solution onto a moving strand, and letting the surplus drip off is another useful coating technique.

A small amount of water increases the solubility of the lubricants, and aids in coating, but the time of contact with water of the suture should be minimized so that if moisture is present in the coating system, the sutures should be dried and desiccated promptly.

In general it is more convenient to use the solvent coating system at levels below 10 percent pick-up and use a heated die at above about 10 percent pick-up.

EXAMPLE 2

A series of runs was made using a coating of two commercial Pluronics F-68 and F-127 on 2/0 size sutures of 6 dpf braided absorbable polyglycolic acid sutures. The coatings were applied by a solution of the Pluronic in chloroform. The concentration of the Pluronic in the solution used for coating is approximately twice that obtained in the braid. A solution containing about 2.8% Pluronic F-68 in chloroform results in about 1.4% Pluronic F-68 on the braid. An adjustment in concentration can be made to secure any desired level. The strand being coated was braided for a 2/0 size suture using a 6 denier per filament extrusion of polyglycolic acid. An uncoated suture strand of the same lot was used as a control. A standard ATLAB yarn Friction Tester Model CS-151-026, Custom Scientific Instruments, Inc. Whippany, New Jersey 07981, with a Hewlett Packard Model 321 dual channel amplifier recorder was used to record the tension of the strand

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feeding into the tester, and coming out of the yarn tester. The chatter factor is the ratio of maximum pull (T_3) to the feed tension (T_1) minus the minimum pull (T_2) to the feed tension, i.e. $(T_3/T_1) - (T_2/T_1)$. The values for friction are of (T_2/T_1) to start slipping.

The values of particular interest are the ratios and percent reduction. With other types of test devices, the numerical values may change, but the relative ratios as

Tests on knot security are dependent on the exact technique of tying knots.

A representative and typical run on knot security showed for a series of tests on size 2/0 polyglycolic acid sutures of 2 denier per filament construction with 4.79% of Pluronic® F-68 coated thereon and different knots, the force in pounds to slip knots or break without slipping to be:

Run	Square Knot	Square + 1 Throw	Square + 2 Throws	Surgeons Knot	Surgeons + 1 Throw	Surgeons + 2 Throws
1	1.70	2.95				
2	2.05	3.90	Broke	Broke	7.90	Broke
3	4.20	4.05	Broke	3.70	Broke	Broke
4	0.70	3.40	Broke	Broke	3.35	Broke
5	3.95	Broke	Broke	1.40	Broke	Broke
Average	2.54	—	—	—	—	—

an index of improvement are analogous.

In this test, an uncut strand, coated as indicated, was used for the test. For use as a suture, such strand is cut to length, needled, packaged and sterilized using conventional techniques. The friction and chatter is more readily measured on continuous lengths.

Reduction in static friction, chatter and the coefficient of friction are shown for typical coating levels, and sutures in Table IV.

EXAMPLE 3

A series of runs, including blank, were made with solutions of the Pluronic® R bioabsorbable lubricant copolymers in chloroform, using the procedures of Example II. The following Table V shows the improvement obtained in chatter and friction with a series of polymers and concentrations.

TABLE IV

POLYGLYCOLIC ACID BRAID
Size 2/0

Run No.	Pluronic Coating	Level %	Static Friction	% Reduction	Chatter Factor	% Reduction	Coeff. of Friction $\times 10^{-2}$	% Reduction
1	Blank	0	3.11		0.50		6.109	
2	Blank	0	3.29		0.60		6.274	
3	F-68	1.39	2.78	13.1	0.30	45.5	5.766	7.0
4	F-68	1.93	2.55	20.3	0.19	65.3	5.468	11.8
5	F-68	4.44	2.54	20.6	0.31	43.6	4.900	20.9
6	F-68	7.29	2.70	15.6	0.33	40.0	5.084	17.9
7	F-68	8.09	2.59	19.1	0.25	54.6	5.424	12.5
8	F-127	1.38	2.55	20.3	0.33	40.0	4.938	20.3
9	F-127	1.57	2.63	17.8	0.24	56.4	5.539	10.6
10	F-127	2.56	2.97	7.2	0.27	30.9	6.104	1.50
11	F-127	5.37	2.76	13.8	0.32	41.8	5.689	8.2
12	F-127	5.62	2.82	11.9	0.40	27.3	5.617	9.4
13	P-127	5.62	2.87	10.3	0.29	47.3	6.007	3.1
14	P-127	8.14	2.81	12.2	0.29	47.3	5.891	4.9
15	F-127	9.83	2.74	14.4	0.29	47.3	5.621	9.3

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TABLE V

POLYGLYCOLIC ACID BRAID
Pluronic® Size 2/0 - 6 denier per filament

Braid	Run	Coating	Level (%)	Static Friction	(%) Reduction	Chatter Factor	(%) Reduction	Coeff. of Friction $\times 10^{-2}$	(%) Reduction
Uncoated	16			3.92		0.31		8.189	
Uncoated	17			3.45		0.21		7.503	
Uncoated	18			2.87		0.27		6.083	
Uncoated	19			2.87		0.18		6.300	
10297B	20	10R8	2.05	2.51	23.4	0.28		5.077	28
10297B	21	10R8	3.00	2.33	28.9	0.16	34.1	4.932	31
10297B	22	10R8	3.96	2.31	29.5	0.21	13.6	4.753	33
10297B	23	10R8	5.31	2.41	26.5	0.23	5.4	4.962	30
10297B	24	10R8	7.49	2.39	27.1	0.25		4.843	32
10297B	25	25R8	2.55	2.34	28.6	0.16	34.1	4.962	30
10297B	26	25R8	3.85	2.40	26.8	0.15	38.3	5.162	27
10297B	27	25R8	6.29	2.23	32.0	0.15	38.3	4.662	34
10297B	28	25R8	7.15	2.31	29.5	0.13	46.5	4.990	30
10297B	29	25R8	8.74	2.37	27.7	0.11	54.7	5.175	27
10297B	30	31R4	2.18	2.53	22.8	0.15	38.3	5.520	22
10297B	31	31R4	3.42	2.53	22.8	0.17	30.0	5.466	23
10297B	32	31R4	4.51	2.57	21.6	0.14	42.4	5.652	23
10297B	33	31R4	5.53	2.61	20.4	0.17	30.0	5.705	20
10297B	34	31R4	7.26	2.51	23.4	0.11	54.7	5.782	19
10297B	35	17R8	2.12	2.45	25.3	0.19	21.8	5.218	27
10297B	36	17R8	3.13	2.45	25.3	0.25		5.019	30
10297B	37	17R8	5.02	2.33	28.9	0.20	17.7	4.782	33
10297B	38	17R8	6.32	2.36	28.0	0.25		4.723	34
10297B	39	17R8	8.60	2.33	28.9	0.15	38.3	4.962	30

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EXAMPLE IV

A braided polyglycolic acid strand, of a size to form a 2/0 USP suture is dipped in a 10% solution of Pluronic F-68 in chloroform, and dried. The pick-up is about 5% by weight of the weight of the strand itself.

The dried coated strand is cut into 54" segments, needled, packaged, sterilized and dried in accordance with conventional procedures.

The thus prepared sutures were used in surgical procedures. When used to approximate tissue at a wound, a suture is placed in an appropriate location, and tied with a square knot. The square knot readily ran down to pull the edges of the wound to the degree of tightness desired by the using surgeon. The suture shows low tissue drag, and excellent knot run down. When a knot is at a desired final location, three additional squared throws are placed to secure the knot. Knots buried in tissue have the lubricant bioabsorbable copolymer removed from the suture surface within 48 hours, which gives additional knot security. The suture itself maintains tissue retaining strength for at least 15 days, and is substantially absorbed in 90 days.

Whereas exemplified and tested with square knots, the ease of knot run-down and reduced tissue drag are useful in most suture placements and for knot retention. The amount of coating, and the relative values for knot run-down and reduced tissue drag, is variable to suit the requirement of a particular surgical situation.

The needling, packaging and sterilizing of the coated sutures is in accordance with conventional procedures.

We claim:

1. An absorbable surgical suture having improved knot run-down characteristics and reduced tissue drag comprising a polyfilamentary synthetic absorbable polymer strand having thereon a thin lubricating coating of a lubricating absorbable copolymer comprising polyoxyethylene blocks and polyoxypropylene blocks to aid run-down and handleability, said bioabsorbable copolymer having a molecular weight such that it is pasty to solid at 25° C.

2. The suture of claim 1 in which the lubricating bioabsorbable polymer has the formula:



where one of R₁ and R₂ is methyl and the other hydrogen, and n and m are sufficiently large that the compound is pasty to solid at 25° C., R is the residue of a relatively low molecular weight reactive hydrogen compound having from 2 to about 6 reactive hydrogen atoms and having not over 6 carbon atoms in said compound, and c is the number of reactive hydrogens on the compound forming R.

3. The suture of claim 1 in which the lubricating bioabsorbable copolymer has effectively the formula:



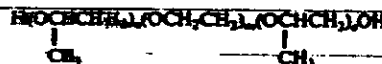
where x, y and z are sufficiently large that the lubricating bioabsorbable copolymer is pasty to solid at 25° C.

4. The suture of claim 3 in which the lubricating bioabsorbable copolymer has a molecular weight of about

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8350 and x and z are about 75 and y about 30, and the melting point is about 52° C.

5. The suture of claim 1 in which the lubricating bioabsorbable copolymer has effectively the formula:

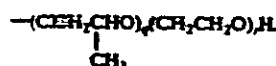


where n, m and e are sufficiently large that the lubricating bioabsorbable copolymer is pasty to solid at 25° C.

6. The suture of claim 1 in which the lubricating bioabsorbable copolymer has effectively the formula:



where R₃ is



where q and r are sufficiently large that the lubricating bioabsorbable copolymer is pasty to solid at 25° C.

7. The suture of claim 1 in which the synthetic absorbable polymer strand is of a tissue absorbable polymer subject to hydrolytic degradation to non-toxic tissue compatible absorbable components, and which polymer has glycolic acid ester linkages.

8. The suture of claim 3 in which the synthetic absorbable polymer strand is of a tissue absorbable polymer subject to hydrolytic degradation to non-toxic tissue compatible absorbable components, and which polymer has glycolic acid ester linkages.

9. The suture of claim 4 in which the synthetic absorbable polymer strand is of a tissue absorbable polymer subject to hydrolytic degradation to non-toxic tissue compatible absorbable components, and which polymer has glycolic acid ester linkages.

10. The suture of claim 7 in which the tissue absorbable polymer is polyglycolic acid.

11. The suture of claim 8 in which the tissue absorbable polymer is polyglycolic acid.

12. The suture of claim 9 in which the tissue absorbable polymer is polyglycolic acid.

13. The suture of claim 1 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

14. The suture of claim 2 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

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15. The suture of claim 3 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

16. The suture of claim 4 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

17. The suture of claim 7 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

18. The suture of claim 8 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

19. The suture of claim 9 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

20. The suture of claim 10 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubri-

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cating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

21. The suture of claim 11 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

22. The suture of claim 12 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

23. A method of closing a wound in living tissue which comprises: sewing edges of a wound in living tissue with the sterile absorbable surgical suture of claim 1,

tying the suture into a square knot, running down the square knot to approximate the tissues in a desired location, placing additional throws on the square knot, and within less than about 48 hours bioabsorbing and removing the lubricant absorbable copolymer from the suture thereby increasing knot security and, leaving the absorbable surgical suture in living tissue until the suture strand is absorbed by living tissue during the healing process, the suture providing useful tissue retention strength for at least 15 days and absorption being substantially complete within 90 days.

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United States Patent [19]

Landi et al.

[11] 4,043,344

[45] Aug. 23, 1977

[54] **NON-ABSORBABLE SURGICAL SUTURES
COATED WITH
POLYOXYETHYLENE-POLYOXYPROPY-
LENE COPOLYMER LUBRICANT**

[75] **Inventors:** Henry Patrick Landi, Yorktown Heights; Vincent Anthony Perciaccante, Long Island City, both of N.Y.

[73] **Assignee:** American Cyanamid Company, Stamford, Conn.

[21] **Appl. No.:** 724,876

[22] **Filed:** Sept. 20, 1976

[51] **Int. Cl.:** A61L 17/00

[52] **U.S. Cl.:** 128/335.5; 128/1 R; 428/375

[58] **Field of Search:** 128/1 R, 335.5; 428/375

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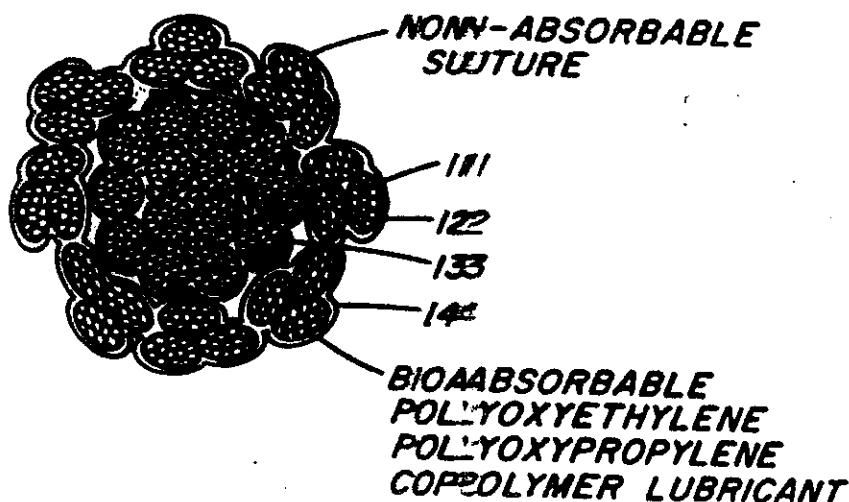
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Primary Examiner—Leland A. Sebastian
Attorney, Agent, or Firm—Charles F. Costello, Jr.

[57] **ABSTRACT**

The handling characteristics, including particularly the knot run down and tissue drag characteristics, of non-absorbable surgical sutures are improved by a coating of a lubricating film of a bioabsorbable copolymer having polyoxyethylene blocks and polyoxypropylene blocks, and which bioabsorbable copolymer has a molecular weight such that it is pasty to solid at 25° C. This lubricant coating is absorbed in tissue in less than about 48 hours—which results in improved long term knot security.

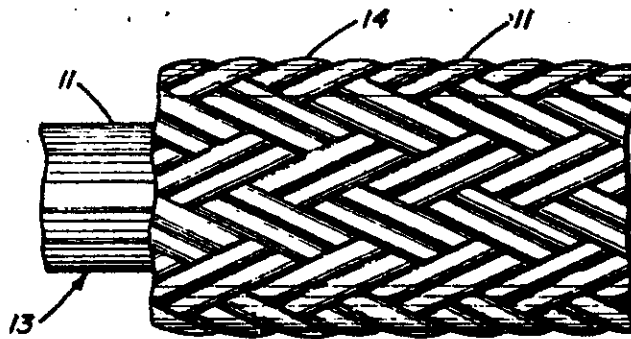
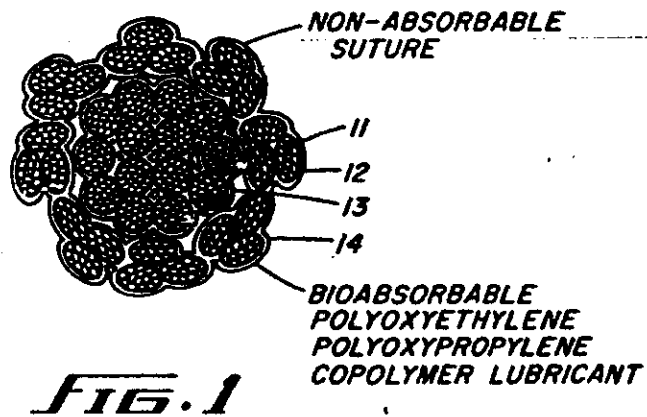
17 Claims, 2 Drawing Figures



U.S. Patent

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NON-ABSORBABLE SURGICAL SUTURES COATED WITH POLYOXYETHYLENE-POLYOXYPROPYLENE COPOLYMER LUBRICANT

BACKGROUND OF THE INVENTION

The handling characteristics of surgical sutures encompass many factors, some of which factors are at least in part inconsistent or seemingly inconsistent. There is a constant effort to improve the handling characteristics. Among the more important of the handling characteristics are those associated with knot run-down. In many surgical procedures it is necessary that a knot be tied in a suture when the knot is deep inside a surgical or natural opening. For instance, a dental surgeon may need to tie a knot inside a patient's mouth. An intravaginal hysterectomy requires suturing in restricted quarters. One technique frequently used is to tie a square knot that can be run-down from an exterior location where the knot is first tied to lie against tissue with a desired degree of tightness. The knot is snugged down so that it is holding with a degree of firmness chosen by the surgeon for a particular situation and then additional throws are tied down against the first throws of the square knot. In some instances, the first throw is a double twist followed by a single throw to form a surgeon's knot, with additional throws to form additional square knots on top as needed. As contrasted with the ease of placement, is the necessity of knot security. Even though it is desired that it be easy to tie a knot, it is mandatory that the knot hold without slipping for an acceptable length of time.

With buried absorbable sutures, the suture including the knot is absorbed, and the knot need only hold until the suture is absorbed. This can be a few hours for certain types of skin incisions, up to 15 to 28 days for some internal knots.

Non-absorbable sutures are used, if strength for a longer time or permanent reinforcement is desired.

Some suture materials are so smooth that a knot run downs very readily and frequently becomes readily untied. Other sutures are of materials in which the knot tends to "lock-up" or refuse to run-down so that it is difficult to snug-down the throws against the tissue and only a few throws are needed, and security is not a problem. Knots in constantly moving tissue, such as adjacent to the heart, particularly if a non-absorbable suture, have a much greater chance of becoming untied than knots in quiescent tissue such as knots holding together a wound inside a plaster cast.

For knots in non-absorbable sutures which are buried in tissue, the problem of knot security for years has been a problem.

PRIOR ART

U.S. Pat. No. 1,254,031 — Jan. 22, 1918, Davis, SUTURE AND METHOD OF MAKING THE SAME, shows a braided collagen suture immersed in collagen or glue to cause close adhesion of the braid, to fill up the interstices and provide a smooth uniform coating.

U.S. Pat. No. 2,576,576 — Nov. 27, 1951, Cresswell and Johnstone, LUBRICATED THREAD, shows a lubricated multifilament collagen thread using as a lubricating film a phosphatide such as lecithin. The lecithin should be applied at the time of coagulation or regeneration of collagen as effective lubrication is not

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obtained if the lubricant is incorporated by adding to a finished thread.

U.S. Pat. No. 2,734,506 — Feb. 14, 1956 — Nichols et al. SILK SUTURES AND LIGATURES shows using poly(alkyl) methacrylate as a coating for silk sutures, and a hot coating die system.

U.S. Pat. No. 3,187,752 — June 8, 1956 — Glick, NON-ABSORBABLE SILICONE COATED SUTURES AND METHOD OF MAKING, shows silk or other non-absorbable synthetic filaments such as nylon, cotton or linen coated with a silicone which gives a more inert suture and reduces capillarity.

U.S. Pat. No. 3,209,589 — Oct. 5, 1965 — Schlatter, YARN FRICTION MEASURING INSTRUMENT, describes a machine for measuring the friction of a yarn sliding over itself and describes the variation of friction with speed, and the "slip-stick" variety at slow speeds.

U.S. Pat. No. 3,297,033 — Jan. 10, 1967 — Schmitt and Polistina, SURGICAL SUTURES, shows synthetic surgical sutures of polyglycolic acid and discloses that the surfaces of the fiber can be coated with a silicone, beeswax, or the like to modify the handling or the absorption rate.

U.S. Pat. No. 3,390,681 — July 2, 1968, Kurtz, POLYESTER SUTURE HAVING IMPROVED KNOTTING CHARACTERISTICS, shows improving the knotting characteristics of a polyester such as one formed from a dicarboxylic acid and a diol (Dacron) by depositing on the fibers a polytetrafluoroethylene (Teflon). This patent discloses many of the problems in suture knots, and is hereby incorporated by this reference thereto. This patent also shows the accepted practice of classing "ligatures" under "sutures" for patent disclosure purposes.

U.S. Pat. No. 3,565,077 — Feb. 23, 1971, Glick, DENSIFIED ABSORBABLE POLYGLYCOLIC ACID SUTURE BRAID, AND METHOD FOR PREPARING SAME, shows a suture construction using polyglycolic acid filaments with a compacted structure and a reduced void fraction.

U.S. Pat. No. 3,813,315, June 11, 1974, Glick, ETHYLENE OXIDE STERILIZATION OF MOISTURE SENSITIVE SURGICAL ELEMENTS shows the desirability of maintaining surgical elements of polymers subject to the hydrolytic degradation to non-toxic, tissue-compatible, absorbable components, such as polyglycolic acid sutures, in a desiccated condition in an air tight container impervious to moisture vapor. Suitable desiccating cycles and foil containers to give products which are storage stable for years are disclosed.

U.S. Pat. No. 3,867,190 — Feb. 18, 1975, Schmitt and Epstein, REDUCING CAPILLARITY OF POLYGLYCOLIC ACID SUTURES, shows the coating of polyglycolic acid surgical sutures with a copolymer of from 15-85% glycolic acid with 85-15% lactic acid which coating fills the interstices of a multi-filament polyglycolic acid suture. Example 10 discloses the coating as minimizing capillarity, and improving run-down. Thicker coatings increase stiffness. This patent has 38 references to earlier prior art on sutures and methods of making them, and related fields and is incorporated herein by this reference thereto. A divisional of said U.S. Pat. No. 3,867,190 is Ser. No. 489,004, July 16, 1974, REDUCING CAPILLARITY OF POLYGLYCOLIC ACID SUTURES, now U.S. Pat. No. 3,982,543 dated Sept. 28, 1976.

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U.S. Pat. No. 3,896,814 — July 29, 1975 — Viviani and Schwartz, COLLAGEN BASED THREADS, shows a collagen or catgut thread which is flexibilized by having therein water and a hygroscopic agent such as a glycerol or a glycol or a low molecular weight (up to 400 m.w.) liquid polyalkylene oxide, and which may additionally be coated with a lipid or a silicone for surface lubricity.

U.S. Pat. No. 3,942,532 — Mar. 9, 1976 — Hamster and Thompson — BRAIDED SUTURE, discloses an adaptation of an INSTRON Universal Testing Instrument using an oscillographic recorder, to use a single throw between two suture strands to measure surface roughness, as an indication of the ease of sliding a single throw knot down the suture into place, there called "tie-down performance." A coating of 0.4 percent to 7 percent of the suture weight of an aliphatic polyester such as a condensate of adipic acid and 1,4-butanediol having a molecular weight of about 2,000-3,000 is recommended.

U.S. Ser. No. 691,749, filed June 1, 1976 — Casey and Epstein — NORMALLY-SOLID BIOABSORBABLE, HYDROLYZABLE, POLYMERIC REACTION PRODUCT, discloses the use of trans-esterification product of poly(1,4-propylene diglycolate) and polyglycolic acid and other trans-esterification products of polyglycolic acid and a polyester of diglycolic acid and an unhindered glycol to coat sutures to improve knot run-down and other suture characteristics.

The coating, coloring and conditioning of surgical sutures with polymeric materials in general is well-known. Silicones, wax, polytetrafluoroethylene, and other polymers have been used. Specific coating materials with unique advantages to give improved sutures are constantly being sought.

SUMMARY OF THE INVENTION

It has now been found that the knot run-down characteristics, handleability, tie-down performance and tissue drag characteristics of braided, twisted or covered multifilament non-absorbable sutures may be improved by coating with a lubricating biologically absorbable copolymer having polyoxyethylene blocks and polyoxypropylene blocks.

Non-absorbable sutures are sutures which are resistant to biodegradation in living mammalian tissue and remain in the tissue as a foreign body, unless surgically removed (e.g. skin sutures) or extruded. An absorbable suture is degraded in body tissues to soluble products and disappears from the implant site, usually within 2 to 6 months. Non-absorbable sutures retain strength in living mammalian tissue for an extended period, often for the life of the subject. Non-absorbable sutures used for skin closures with the knot above the surface of the skin are removed by the surgeon at a suitable stage of the healing process. For those in which the knot in the non-absorbable suture is buried in living tissue, and are to be left indefinitely, the present lubricant is absorbed from the non-absorbable suture in less than about 48 hours, and hence the lubricating action ceases, and knot security improves.

Non-absorbable sutures are typically of silk, cotton, nylon, a non-absorbable polyester (Dacron®) polypropylene, polyethylene, or linen. Even metals such as stainless steel, monofilament or braided or tantalum or platinum have been used.

Absorbable or bioabsorbable as applied to the coating, refers to a coating which by hydrolytic or enzymatic

degradation, or by its inherent characteristic, has such molecular weight and solubility properties that it is absorbed from the surface of the suture and is eliminated by the subject either unchanged or in hydrolyzed or degraded form.

The lubricant coating not only aids in the knot run-down characteristics but increases the smoothness and flexibility of the sutures so that they may be more easily drawn through the skin and other tissues during placement of the suture. This reduction in friction is called reduced tissue drag. The coating that aids in reduced tissue drag, and lubricates in knot placement also causes the knot to slip more readily.

Another unexpected and unobvious advantage of the present lubricant coating is that the lubricant copolymers are absorbed from the suture within a few days so as the wound heals knot security improves.

The absorbable coating is one or more of a group of compounds having blocks of polyoxyethylene and blocks of polyoxypropylene in their structure. For simplicity and ease of description these compounds are taught, drawn and treated as if there were merely two or three blocks in the chain. However, it is to be understood that non-significant quantities of polyoxypropylene may be present in the polyoxyethylene block and minor quantities of polyoxyethylene may be present in the polyoxypropylene block. From the methods of manufacture it would appear that there may be and probably are such minor admixtures present in the chain. The commercially available grades are acceptable and found to have a low and acceptable degree of toxicity.

The present lubricants may be indicated as having the formula:



where one of R₁ and R₂ is methyl and the other hydrogen, and n and m are sufficiently large that the compound is pasty to solid at 25° C., R is the residue of a relatively low molecular weight reactive hydrogen compound having from 2 to about 6 reactive hydrogen atoms and having not over 6 carbon atoms in said compound, and c is the number of reactive hydrogens on the compound forming R. Those compounds which are at least pasty at 25° C. are preferred because they adhere better to the synthetic absorbable polyfilamentary suture. There is not a sharp cut off, but in general as the materials become more pasty or solid, their effectiveness improves.

The lubricant compound and methods of manufacture are described at length in certain prior art. The Pluronics in general are described in U.S. Pat. No. 2,674,619, Apr. 6, 1954, POLYOXYALKYLENE COMPOUNDS, L. G. Lundsted. These are referred to as a cogeneric mixture of conjugated polyoxypropylene-polyoxyethylene compounds and are further described therein.

Certain nitrogen containing polyoxyethylene detergent compositions which are here useful as lubricants are described in U.S. Pat. No. 2,979,528, Apr. 11, 1961, NITROGEN-CONTAINING POLYOXYALKYLENE DETERGENT COMPOSITIONS, L. G. Lundsted. Column 4, lines 44-58 of this patent disclose that the oxypropylene chains may have a small amount of ethyleneoxide therein and vice versa. Because of the sources of ethylene oxide and propylene oxide, usually

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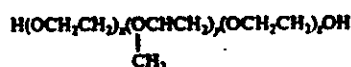
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from petroleum fractions, it is to be expected that in commercial practice complete rectification to chemically pure compounds is not obtained. Fortunately the commercial grades may be used on sutures with excellent results. Said U.S. Pat. No. 2,979,528 also points out that as polymers, all molecular species are far from identical—some chains are shorter, some are longer, but on the average the materials are as indicated and it is the physical properties of the lubricants, not the molecular weight spread of the components, which are important.

U.S. Pat. No. 3,036,118, May 22, 1962, MIXTURES OF NOVEL CONJUGATED POLYOXYETHYLENE-POLYOXYPROPYLENE COMPOUNDS, D. R. Jackson and L. G. Lundstedt, has much disclosure on the addition of polyoxyethylene groups and polyoxypropylene groups to reactive hydrogen compounds having from 2 to 6 reactive hydrogen atoms and not over 6 carbon atoms per molecule. Among other such compounds are listed the group consisting of aliphatic polyhydric alcohols, alkylamines, alkylene polyamines, cyclic amines, amides, and polycarboxylic acids, oxyethylene groups and oxypropylene groups. The reactive hydrogen compound serves as a chain initiator and can be present in such a small proportion that it has minor significance in its own right and serves mainly as a foundation on which the predominantly polyoxyethylene or polyoxypropylene blocks may be added in the chosen order. Whereas U.S. Pat. No. 3,036,118 claims primarily the Reverse Pluronics in which the polyoxyethylene chains are attached to the nucleus or initiating reactive hydrogen compounds, in the present invention either the Reverse Pluronic with the polyoxyethylene in the center or the regular Pluronics with the polyoxypropylene in the center or the Tetronics with nitrogen in the center may be used for lubricant purposes.

Because the chemistry is previously known, and to avoid unnecessarily extending the length of the present disclosure, the disclosures of each of these three patents is herein hereby incorporated by this reference thereto.

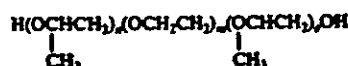
These lubricating bioabsorbable copolymers are often classed as surface active agents as the polyoxyethylene blocks are predominantly hydrophilic and the polyoxypropylene blocks are predominantly hydrophobic. The materials have been sold by the Wyandotte Chemical Company under the trademark of PLURONICS for the formula:



where x , y and z are whole numbers.

REVERSE PLURONICS for the formula:

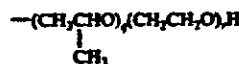
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where n , m and o are whole numbers and TETRONICS for the formula:



where R_1 is



where g and r are whole numbers.

For the present purposes as lubricants for non-absorbable sutures, the values of x , y , z , n , m , o , g and r are such that the lubricants are pasty to solid at 25° C.

The pastes are opaque semi-solids with melting points above room temperature—preferably above about 40° C.

Those classed as Pluronics are particularly useful for the present invention.

The physical characteristics of these lubricant compounds are affected by their total molecular weight and by the percentage of polyoxyethylene in the molecule. References are made to the commercially available compounds for purposes of convenience. Those which are liquid normally have an L as a primary designator, those which are pasty have a P and those which are solid have an F. For the Pluronics, the first number indicates the typical molecular weight of the polyoxypropylene hydrophobic portion with a number 3 being about 950; 4 being about 1200; 5 being about 1450; 6 about 1750; 7 about 2050; 8 about 2250; 9 about 2750; 10 about 3250; 11 about 3625 and 12 about 4000. The second digit indicates the approximate percentage of the polyoxyethylene hydrophilic units in the total molecular, in units of 10. Thus for example, the formulations of certain commercially available products is approximately that shown in Table I.

As all compositions are mixtures, all values are approximate, and values are subject to some rounding.

Additional data is given in The Journal of the American Medical Association, volume 217, pages 469 to 470 (1971) where the new nonproprietary name of POLOX-AMER is established for these compositions as direct food additives.

TABLE I

PLURONIC	Average Molecular Weight	M.W. of each Polyoxyethylene Block	Units of each x and z	% Polyoxyethylene	M.W. of Polyoxypropylene Block	Units of y	M.P. °C.
F-38	5000	2000	46	80	930	16	43
F-68	8350	3300	75	80	1,750	30	52
F-77	6600	2300	52	70	2,050	35	48
P-85	4600	1200	27	50	2,250	39	40
F-87	7700	2700	62	70	2,250	39	49
F-88	10800	4300	97	80	2,250	39	54
F-92	13500	5400	122	80	2,750	47	55
F-108	14400	5600	128	80	3,150	54	57
F-127	12500	4300	98	70	3,900	67	56

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TABLE I-continued

REVERSE PLURONIC	M.W. polyethylene units of m block	M.W. polyoxypropylene block	Units of n and O
10R8	3,000	2000	45
17R8	4,350	2600	59
25R8	9,000	3250	74
		65%	65%
		60%	60%
		57%	57%
		562	9
		670	15
		1250	22
			46
			53
			56

TETRONIC	Average Molecular Weight	Approximate Molecular Weight of Individual Polyoxethylene Block	Approximate % Polyoxethylene	Molecular Approximate Weight of Individual Polyoxpropylene Block	Approximate % Polyoxpropylene	Average Approximate length of chains per block Units of r	Units of q
707	12,000	2312	74	673	26	52.5	11
908	26,100	5588	85	923	15	127	15.9
1107	14,500	2438	67	1173	33	55.4	20.2
1307	18,600	3213	69	1423	31	73	24.5
1508	27,000	5063	75	1673	25	115	28.5

In general, the Pluronics with a molecular weight range of from about 4,750 to 16,250 are waxy solids. The polyoxypropylene portion has a molecular weight of 950 to 4,000 and the polyoxethylene content of about 60-80%.

The pastes in general have a total molecular weight ranging from 3,500 to 5,700 with a polyoxypropylene molecular weight range of 1,750 to 6,500 and polyoxethylene content of 30 to 50%. The transitions from wax to paste to liquid are not sharp.

COATING

The non-absorbable suture is conveniently coated by several conventional procedures including:

Melt Coating

The uncoated suture is placed in a split die whose orifice corresponds to diameter specifications for the particular size suture to be coated. The die is then clamped in a heating block and the polyoxethylene-polyoxypropylene lubricant bioabsorbable copolymer placed in the die. The die is raised to a temperature about 20° C. above the melting point of said copolymer and after the copolymer has melted, the suture to be coated is slowly pulled downward through the molten material in the die and collected on a take-up spool. The spool is mounted directly below the die a sufficient distance to allow solidification of the coated. A cooling tunnel or a blast of cooling air may be used to increase production speeds. Nichols et al. U.S. Pat. No. 2,734,506, supra, describes one useful apparatus for coating.

Solution Coating

The polyoxethylene-polyoxypropylene lubricant bioabsorbable copolymer is dissolved in chloroform. About twice the percentage by weight is used for coating solution as is desired on the final sutures. A feed loop such as a loop of wire or a ceramic is threaded with the uncoated suture, after which the feed loop is then submerged in the solution and the suture is passed down through the feed loop. It may be passed through a die whose diameter is such that after drying a suture will have the desired diameter. The suture is pulled slowly through the solution and at least partially dried in a drying tunnel. The drying is finished after the suture is wound on a spool. Because variations in equipment, speed, and temperature affect the pick-up of the lubricant bioabsorbable polymer, the concentration in the coating is adjusted based on a preliminary run or experience.

Other coating techniques which are well known in the coating of polyfilamentary strands may be used. The

techniques used for insulating wire may be adapted for large scale suture manufacture. The above are merely two of the more convenient and well known methods for coating. Details are later illustrated in examples.

TOXICITY

The low toxicity of the polyoxethylene-polyoxypropylene compounds of the present invention are shown in such U.S. Pats. as U.S. Pat. No. 3,450,502 which describes the use of a copolymer having a total molecular weight of about 8,750 in isotonic solutions used as a priming agent in a heart-lung apparatus. In sutures even if a maximum of around 25-30% by weight of the suture of copolymer is used, only a very small amount is placed in the subject.

The low toxicity is shown in the following table.

TABLE II

TOXICITY

Pluronic No.	Total Molecular Weight	Physical Characteristic	LD 50 (gm/kg) in Mice
F-38	5000	wax	>5
F-77	6600	wax	4.2
F-87	7700	wax	3.75
F-6*	8350	wax	>5
F-34	10800	wax	>5
F-127	12500	wax	2.25
F-98	13900	wax	>5
F-108	14400	wax	1.25
P-45	3400	paste	0.83
P-84	4200	paste	0.4
P-85	4600	paste	0.53
P-94	4600	paste	0.6
P-103	4950	paste	1.4
P-104	5850	paste	0.75
P-123	5750	paste	2.7
P-105	6500	paste	3

The polyoxethylene-polyoxypropylene compositions used as the lubricant bioabsorbable copolymers have been used in food products; and have been the subject of studies as to their elimination from a mammalian body. In general, they are eliminated in the urine fairly rapidly, and within 48 hours nearly all have been eliminated from the blood stream.

If some of the lubricant bioabsorbable copolymer is trapped in braid pores of a suture, the rate of diffusion into the blood stream may be reduced and hence the time for elimination somewhat increased. The molecular weight is small enough that the lubricant bioabsorbable copolymers may be eliminated unchanged, although some degradation may occur before elimination. The important thing is that the lubricant bioabsorbable copolymer has no deleterious effect upon healing tissues adjacent to the sutures, and being removed from the surface of the suture by absorption by the body, not

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security is improved. As soon as suture placement is completed, the knot run down and tissue drag reduction function is complete, and as the lubricant bioabsorbable copolymer is removed from the suture, knot security improves.

Definitions in the suture and textile trades are sometimes ambiguous or confused. As herein used;

A "filament" is a single, long, thin flexible structure of a non-absorbable or absorbable material. It may be continuous or staple.

"Staple" is used to designate a group of shorter filaments which are usually twisted together to form a longer continuous thread.

An absorbable filament is one which is absorbed, that is digested or dissolved, in living mammalian tissue.

A "thread" is a plurality of filaments, either continuous or staple, twisted together.

A "strand" is a plurality of filaments or threads twisted, plaited, braided, or laid parallel to form a unit for further construction into a fabric, or used per se, or a monofilament of such size as to be woven or used independently.

The term "suture" is used to include the term "ligature" as technically a suture is used with a needle whereas the ligature is merely used to tie without being placed by a needle.

A finished suture has a needle attached and is sterile and ready for use in surgery. For purposes of convenience in nomenclature, the term "suture" is frequently used to refer to the same strand before it is coated and before it is packaged and sterilized. Context indicates whether it is the sterile suture ready for use, or the suture in a manufacturing step which is referred to.

The strand of the suture is used as the basis for weight in determining the quantity of material that is placed on the non-absorbable strand in forming the non-absorbable surgical suture.

The quantity of the lubricating bioabsorbable copolymer is from about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer based on the weight of the uncoated strand forming the suture. It is not necessary that the coating be continuous as a discontinuous coating on the surface aids in reducing friction and chatter. A larger quantity may be present if the lubricating bioabsorbable copolymer penetrates inside the strand, with the various filaments themselves being partially or totally covered.

The wide range of coating weight permits adaptation of the present sutures to many varied uses. Because the strand to be coated to form the suture may have considerable variation in surface roughness, due to the mechanical structure, i.e. braid or twist, etc. as well as being made from filaments which are less than 2 denier per filament to more than 6 denier per filament, with the finer filament sizes giving a smoother surface; and because the filaments may be stretched after the suture is manufactured or in heat treatment, the surface roughness basically can vary. The smoother surfaces require less of the lubricating bioabsorbable copolymer for analogous degrees of slippage.

The various surgical techniques used interact with the desired degree of lubrication. For any given type of knot, a larger quantity of lubricant which for a particular technique increases the ease of run-down, also increases the ease of the knot running back or slipping, called knot security. For some surgical procedures it is highly desirable that the knot be very free in running down, even though the knot slips more readily.

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A surgeon in tying knots is confronted with the interaction between the method of tying the knot and the ease of slipping. If a suture is comparatively well lubricated, the surgeon can use a square knot, which is run down readily; with additional squared throws for knot security. On the other hand, if the suture is less well lubricated, the surgeon can use a double half-hitch or some other type of knot which moves more readily to run the knot down to position, after which the double half hitch can be pulled to square the knot, or additional throws can be thrown down against the knot to give adequate knot security. Thus the surgeon can either adapt his knot techniques to a particular suture, or can get sutures whose surface lubricity is best adapted to the technique which the surgeon desires to use. Generally, there is an adaptation of each to the other. The surgeon attempts to get a suture whose characteristics are those which he prefers, and then adapts his knot tying techniques to the sutures that he has at the time. Some surgeons make very successful knots with stainless steel wire using a knotting technique that is adapted to such a wire which has very poor run-down. Others prefer a much more readily run-down well-lubricated suture.

Additionally the location of use has influences. Sometimes a suture in passing through tissue picks up tissue fluids. The suture may be coated with tissue fluids which are either fresh or partly dry at the time the knot is tied. In some surgical techniques it is necessary to preplace the sutures, and tie the suture after the coating of tissue fluids on the suture has a chance to become at least partially dried.

Because the ease of knot run-down and knot security are somewhat opposite, it is necessary for the surgeon to use additional throws or such knots as will hold under the particular conditions of a selected surgical procedure. By changing the quantity of the lubricant bioabsorbable copolymer, the run-down can be modified to suit a surgeon's preference.

The time of use of the knots can be quite varied. Some surgeons use a suture to ligate bleeders in a wound with a retention requirement of 30 minutes or less. Such knots can be removed as the surgical procedure is complete, and before wound closure. Others leave the knots in the tissue even though there is no likelihood that a bleeder would reopen.

Because the present lubricating bioabsorbable copolymer is removed from the suture in living tissue, as the lubricant is removed the knot security increases and after 48 hours more or less, knot security is greatly improved.

The examples following should show the effects of certain different coating and quantities under certain conditions.

The requirements of surgery are extremely varied, and various coating weights permit adaptation of non-absorbable sutures to different conditions.

In general, if the surgeon desires a better lubricated suture, a larger quantity of the lubricating bioabsorbable copolymer is used and conversely if the surgeon is willing to accept slightly reduced knot run-down and tissue drag characteristics in favor of greater knot security, the coating level is reduced in favor of this particular compromise.

Usually from 2 percent to 8 percent of the lubricant bioabsorbable copolymer gives a useful range of compromise between the ease of knot run-down and knot security.

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A usage of about 5 percent by weight of Pluronic F-68 is a preferred compromise between the knot run-down and knot security requirements for 2 to 6 denier per filament braided sutures of polyglycolic acid.

In the Drawings:

FIG. 1 is cross-section of a non-absorbable suture having on the surface thereof a bioabsorbable polyoxyethylene polyoxypropylene copolymer lubricant.

FIG. 2 is a drawing of a suture showing the parallel filaments in the core and the braided sheath. The lubricant coating appears on the surface.

The drawings are diagrammatic and representative. The filaments 11 of the non-absorbable suture are at best somewhat jumbled in actual configuration but are illustrated as patterned in a somewhat idealized style. The coating 12 of the lubricant bioabsorbable polyoxyethylene-polyoxypropylene copolymer is shown much exaggerated. At a level of from 0.1 to 25 percent, the coating would be so thin as to merely be represented by a blurred line if to accurate scale.

In FIG. 2 the core 13 of the braided suture consists of parallel filaments and the sheath 14 consists of a plurality of filaments, typically braided in configuration. The type of braid shown is representative and diagrammatic. The visibility and appearance of the coating varies depending upon the observational technique used to inspect the suture.

The coating 12 in part may bridge the gap between

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Also 5 runs were made using a commercial silicone coated silk suture, see U.S. Pat. No. 3,187,752, *supra*, for comparative purposes.

For these coatings, the braid was run through a solution of the Pluronic in chloroform at a concentration of about twice the percentage desired for the coating on the suture, and air dried.

A standard ATLAB yarn Friction Tester Model CS-152-026, Custom Scientific Instruments, Inc. Whippany, New Jersey 07981, with a Hewlett Packard Model 321 dual channel amplifier recorder was used to record the tension of the strand feeding into the tester, and coming out of the yarn tester. The chatter factor is the ratio of maximum pull (T_2) to the feed tension (T_1) minus the minimum pull (T_2) to the feed tension, i.e. $(T_2/T_1) - (T_2/T_1)$. The values for friction are of (T_2/T_1) to start slipping.

The values of particular interest are the ratios and percent reduction. With other types of test devices, the numerical values may change, but the relative ratios as an index of improvement are analogous.

In this test, an uncut strand, coated as indicated, was used for the test. For use as a suture, such strand is cut to length, needled, packaged and sterilized using conventional techniques. The friction and chatter is more readily measured on continuous lengths.

Reduction in static friction, chatter and the coefficient of friction are shown in Table III.

TABLE III

Run No.	Pluronic Coating	Level (%)	Static Friction	Size 2/0 Silk Braid % Reduction	Chatter Factor	% Reduction	Coeff. of Friction $\times 10^{-2}$	% Reduction
1	Blank	—	3.15	—	0.46	—	6.300	—
2	Blank	—	3.40	—	0.47	—	6.822	—
3	Blank	—	3.32	—	0.46	—	6.490	—
4	Blank	—	3.78	—	0.93	—	6.666	—
5	Silicone	—	3.75	—	0.66	—	7.205	—
6	Silicone	—	3.60	—	0.63	—	6.930	—
7	Silicone	—	3.63	—	0.74	—	6.756	—
8	Silicone	—	3.63	—	0.63	—	7.015	—
9	Silicone	—	3.56	—	0.89	—	6.156	—
10	F-68	2.46	2.85	16.4	0.13	—	6.370	3.77
11	F-68	3.09	2.46	27.0	0.09	—	5.520	16.6
12	F-68	3.51	2.34	31.4	0.07	—	5.190	21.6
13	F-68	3.51	2.44	28.5	0.08	—	5.466	17.4
14	F-68	4.43	2.49	27.0	0.10	—	5.546	16.2
15	F-127	1.68	2.51	26.4	0.08	77.6	5.652	14.6
16	F-127	1.68	2.41	29.3	0.05	91.4	5.466	17.4
17	F-127	2.57	2.51	26.4	0.06	89.7	5.652	14.6
18	F-127	2.57	2.40	29.6	0.05	84.4	5.329	19.5
19	F-127	4.16	2.53	25.8	0.07	87.9	5.782	12.7
20	F-127	4.16	2.39	29.9	0.05	91.4	5.412	18.2
21	F-127	5.16	2.48	27.3	0.06	89.7	5.626	15.0
22	F-127	5.16	2.38	30.2	0.05	91.4	5.357	19.1
23	F-127	5.95	2.45	28.2	0.10	82.8	5.412	18.2
24	F-127	5.95	2.52	26.1	0.07	87.9	5.705	13.8
25	F-127	5.95	2.43	28.7	0.04	93.1	5.520	16.6
26	F-127	7.72	2.43	28.7	0.08	86.2	5.439	17.8

the individual filaments in the finished suture. Depending upon the quantity of coating used, the bridging may be more or less complete but complete filling is not necessary. If the coating level is increased, knot run-down continues to be improved, but knot security is compromised.

EXAMPLE 1

Friction and Chatter Tests

A set of 2/0 USP XIX (diameter 0.339 mm, maximum) braided silk sutures was coated with 5 levels of Pluronic F-68; and 12 levels of Pluronic F-127.

4 Blanks were run with no coating, on braid from the same lot, for comparison, and an average of these 4 used for comparative values.

With other braid constructions and other sizes, the relative ease of knot run-down may be greater or less for the same quantity of coating, or conversely the quantity of the coating may be adjusted to give the desired knot run-down values.

The quantity of the Pluronic in the solvent may be varied, and solvents other than chloroform may be used.

Other organic solvents such as methyl alcohol, ethyl alcohol, isopropyl alcohol, methylene chloride, warm xylene (about 60° C.), tetrahydrofuran, acetone, dimethylformamide, dimethyl sulfoxide, mixtures thereof, and other similar solvents for the lubricant may be used for coating. Flowing the solution onto a moving strand, and letting the surplus drip off is another useful coating technique.

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A small amount of water increases the solubility of the lubricants, and aids in coating.

In general it is more convenient to use the solvent coating systems at levels below 10 percent pick-up and use a heated die at above about 10 percent pick-up.

EXAMPLE 2

2/0 Nylon Braided Sutures

Using the procedures described in Example 1, runs were made on nylon braid, sized for a 2/0 suture. The reduction in friction, and chatter factors are shown in Table IV. Both uncoated braids from the same lot, and commercial silicone coated nylon were used for comparison.

The reduction in chatter is particularly outstanding.

TABLE IV

Pluronic Run No.	Level Coating	Static (%)	% Friction	2/0 NYLON BRAID Chatter Reduction	% Factor	Coeff. of Reduction	% Friction $\times 10^{-2}$	% Reduction
1	Blank	—	3.02	—	0.33	—	6.300	—
2	Blank	—	2.89	—	0.53	—	6.205	—
3	Blank	—	3.06	—	0.51	—	5.933	—
4	Silicone	—	2.69	10.0	0.34	26.1	5.446	11.1
5	Silicone	—	2.89	3.34	0.42	1.69	5.762	6.25
6	Silicone	—	3.43	—	0.55	—	6.734	—
7	F-68	2.53	2.24	25.1	0.19	60.9	4.632	24.6
8	F-68	2.53	2.47	17.4	0.23	30.0	5.162	16.0
9	F-68	2.53	2.43	18.7	0.16	65.2	5.218	15.1
10	F-68	4.91	2.41	19.4	0.23	30.0	4.942	19.6
11	F-68	5.60	2.29	23.4	0.18	60.9	4.726	23.1
12	F-68	5.60	2.42	19.1	0.20	36.5	5.077	17.4
13	F-68	5.60	2.46	17.1	0.17	63.0	5.274	14.2
14	F-68	6.09	2.54	15.1	0.22	52.2	5.347	13.0
15	F-127	2.83	2.49	16.7	0.19	38.7	5.302	13.7
16	F-127	3.08	2.32	22.4	0.22	52.2	4.783	22.2
17	F-127	3.36	2.36	21.1	0.17	63.0	4.989	18.8
18	F-127	5.60	2.37	20.7	0.17	63.0	4.989	18.8
19	F-127	5.60	2.36	21.1	0.12	73.9	5.133	16.5
20	F-127	5.60	2.38	20.4	0.13	71.7	5.162	16.0
21	F-127	6.21	2.37	20.7	0.15	67.4	5.077	17.4
22	F-127	6.79	2.45	18.1	0.14	69.6	5.329	13.3
23	F-127	7.57	2.65	11.4	0.28	39.1	5.520	10.2

EXAMPLE 3

2/0 Dacron® Braided Sutures

Using the procedure of Example 1, runs were made on a polyester braid (Dacron®) sized for a 2/0 suture. The reduction in friction and chatter factor are shown in Table V.

Both uncoated braid from the same lot and silicone coated braid were used for comparison. An average of the uncoated braid runs was used as a base to show improvement.

TABLE V

Run No.	Pluronic Coating	Level (%)	Static Friction	2/0 Dacron Braid % Chatter Reduction	% Factor	Coeff. of Reduction	% Friction $\times 10^{-2}$	% Reduction
1	Blank	—	2.89	—	0.31	—	6.027	—
2	Blank	—	2.65	—	0.34	—	5.310	—
3	Blank	—	2.54	—	0.28	—	5.189	—
4	Silicone	—	2.14	—	0.19	—	4.263	—
5	Silicone	—	2.20	—	0.17	—	4.478	—
6	Silicone	—	2.40	—	0.27	—	4.800	—
7	F-127	2.39	2.60	3.45	0.33	—	5.216	9.30
8	F-127	3.37	2.47	8.28	0.21	32.3	4.996	9.30
9	F-127	3.12	2.36	12.4	0.21	32.3	4.871	11.4
10	F-68	4.03	2.20	18.3	0.19	38.7	4.269	22.5
11	F-68	4.03	2.28	15.3	0.21	32.3	4.628	16.0
12	F-68	5.04	2.45	9.02	0.19	38.7	5.084	7.70
13	F-68	6.26	2.74	16.8	0.18	41.9	4.580	16.8
14	F-68	6.98	2.52	6.42	0.24	22.6	5.247	4.74
15	F-68	8.59	2.26	16.1	0.14	54.8	4.785	13.1

The data in the example is illustrative. Reductions in frictions and improvement in chatter is obtained on all

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sizes of sutures. With different materials and constructions the results may vary.

The amount of coating and the ease of run-down can be varied to give results desired by the using surgeons.

For sutures, either absorbable or non-absorbable, in which capillarity is a problem, a coating of a phosphatide, preferably purified lecithin, such as taught by U.S. Pat. No. 2,576,576 may be used to reduce capillarity and friction, with the present coating as an additional friction reductant. Lecithin causes tissue irritation under some conditions, particularly if not pure.

EXAMPLE IV

A braided silk suture strand, of a size to form a 2/0 USP suture, is dipped in a 10% solution of Pluronic

F-68 in chloroform, and dried. The pick up is about 5% by weight of the weight of the strand itself.

The dried coated strand is cut into 54 inch segments, needled, packaged, sterilized and dried in accordance with conventional procedures.

The thus prepared silk sutures are used in surgical procedures. When used to approximate tissue at a wound, a suture is placed in an appropriate location, and tied with a square knot. The square knot readily runs down to pull the edges of the wound to the degree of tightness desired by the using surgeon. The suture shows low tissue drag, and excellent knot run down.

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When a knot is at a desired final location, three additional squared throws are placed to secure the knot. Knots buried in tissue have the lubricant bioabsorbable

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copolymer removed from the suture surface within 48 hours, which gives additional knot security.

When removed from test animals after 48 hours, a square knot, without additional throws shows markedly greater knot security than immediately after placement.

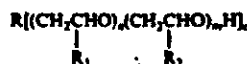
In human tissue, in so far as can be observed, the knot security increases as the bioabsorbable lubricant coating is absorbed in tissue.

Whereas exemplified and tested with square knots, the ease of knot run-down and reduced tissue drag are useful in most suture placements and for knot retention. The amount of coating, and the relative values for knot run-down and reduced tissue drag, is variable to suit the requirement of a particular surgical situation.

The needling, packaging and sterilizing of the coated sutures is in accordance with conventional procedures. We claim:

1. A non-absorbable surgical suture having improved knot run-down characteristics and reduced tissue drag comprising a polyfilamentary non-absorbable strand having thereon a thin lubricating coating of a lubricating absorbable co-polymer comprising polyoxyethylene blocks and polyoxypropylene blocks to aid run-down and handleability, said bioabsorbable copolymer having a molecular weight such that it is pasty to solid at 25° C.

2. The suture of claim 1 in which the lubricating bioabsorbable polymer has the formula:



where one of R₁ and R₂ is methyl and the other hydrogen, and *n* and *m* are sufficiently large that the compound is pasty to solid at 25° C., R is the residue of a relatively low molecular weight reactive hydrogen compound having from 2 to about 6 reactive hydrogen atoms and having not over 6 carbon atoms in said compound, and *c* is the number of reactive hydrogens on the compound forming R.

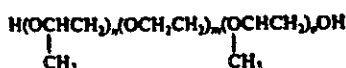
3. The suture of claim 1 in which the lubricating bioabsorbable copolymer has effectively the formula:



where *x*, *y* and *z* are sufficiently large that the lubricating bioabsorbable copolymer is pasty to solid at 25° C.

4. The suture of claim 3 in which the lubricating bioabsorbable copolymer has a molecular weight of about 8350 and *x* and *z* are about 75 and *y* about 30, and the melting point is about 52° C.

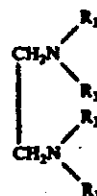
5. The suture of claim 1 in which the lubricating bioabsorbable copolymer has effectively the formula:



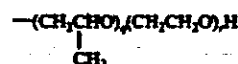
where *n*, *m* and *o* are sufficiently large that the lubricating bioabsorbable copolymer is pasty to solid at 25° C.

6. The suture of claim 1 in which the lubricating bioabsorbable copolymer has effectively the formula:

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where R₃ is



where *q* and *r* are sufficiently large that the lubricating bioabsorbable copolymer is pasty to solid at 25° C.

7. The suture of claim 1 in which the non-absorbable strand is selected from the group consisting of silk, cotton, nylon, a non-absorbable polyester, polypropylene and polyethylene.

8. The suture of claim 3 in which the non-absorbable strand is selected from the group consisting of silk, cotton, nylon, a non-absorbable polyester, polypropylene and polyethylene.

9. The suture of claim 4 in which the non-absorbable strand is selected from the group consisting of silk, cotton, nylon, a non-absorbable polyester, polypropylene and polyethylene.

10. The suture of claim 1 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

11. The suture of claim 2 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

12. The suture of claim 3 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

13. The suture of claim 4 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

14. The suture of claim 7 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

15. The suture of claim 8 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the

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uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

16. The suture of claim 9 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

17. A method of closing a wound in living tissue which comprises: sewing edges of a wound in living

tissue with the sterile non-absorbable surgical suture of claim 1,

tying the suture into a square knot,

running down the square knot to approximate the tissues in a desired location,

placing additional throws on the square knot, in a subcutaneous location, and

within less than about 48 hours bioabsorbing and removing the lubricant absorbable copolymer from the suture thereby increasing knot security, and leaving the non-absorbable surgical suture in living tissue, thereby reinforcing the tissue.

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United States Patent [19]

Ohi et al.

[111] Patent Number: **4,946,467**[445] Date of Patent: **Aug. 7, 1990**[54] **SURGICAL SUTURE**

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[21] Appl. No.: 320,529

[22] Filed: Mar. 8, 1989

[30] Foreign Application Priority Data

Mar. 14, 1988 [JP] Japan 63-34397[U]

[51] Int. Cl.³ A61B 17/00

[52] U.S. Cl. 606/228

[58] Field of Search 128/335.5; 606/228

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Assistant Examiner—Gary Jackson

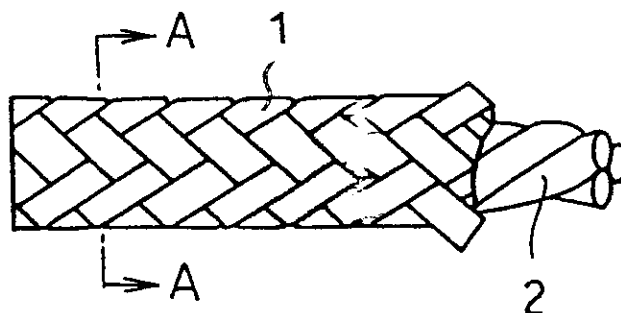
Attorney, Agent, or Firm—Armstrong, Nikaido,

Marmelstein, Kubovcik & Murray

[57] ABSTRACT

A suture comprising a core of at least one synthetic fiber filament yarns, and a covering layer formed of a plurality of silk strands and sheathing the core, the core and the covering layer having substantially the same elongation at break. The filament yarns have increased modulus of elasticity and increased breaking strength to thereby give the suture improved breaking strength and also have enhanced rigidity to render the suture highly amenable to the correction of its deformation and easier to handle.

10 Claims, 2 Drawing Sheets



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FIG. 1

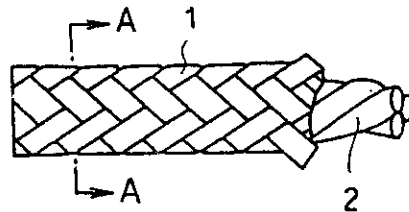


FIG. 2

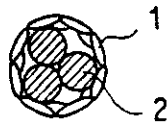


FIG. 3



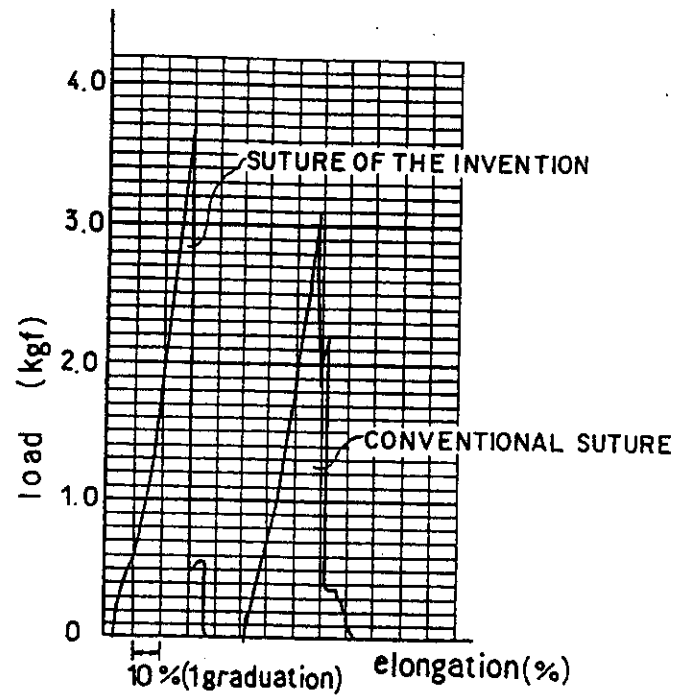
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FIG. 4



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SURGICAL SUTURE

BACKGROUND OF THE INVENTION

1. Field of Invention

The present invention relates to sutures for use in surgery.

2. Description of the Prior Art

Sutures of silk have long been known and used for various surgical applications. Conventional sutures are of various types and include those prepared by twisting, braids formed by plaiting, and braids having a core. The known suture is made of silk only and therefore has the drawback of being low in stiffness and having very poor ability to restore itself when deformed. For example, the suture wound on a reel remains helically curled when unwound therefrom and is difficult to straighten to a correct form. The same difficulty is also encountered with the suture wound around a paper core.

If the suture is used as curled the suture will coil around the hand of the surgeon or hang down in a helical form due to its excessive flexibility and causes great frustration to the surgeon.

To overcome this problem, we have proposed a suture comprising a core of synthetic fiber filament yarn and a braid or mesh like of silk strands covering the core (Japanese Utility Model Application No. 41670/1987). The proposed suture is given suitable flexibility due to the appropriate rigidity of the filament yarn as afforded by doubled polyester filament strands in combination with the flexibility of the silk strands covering the yarn, whereby the suture is made amenable to the correction of its deformation such as the curl due to winding so as to be easily handled. Furthermore, the suture has a higher breaking strength than those consisting solely of silk strands owing to the presence of the core of synthetic fiber filament yarn. However, the suture still remains to be improved since there is a demand for sutures having higher strength.

SUMMARY OF THE INVENTION

The main object of the present invention is to provide a surgical suture meeting this demand, and more particularly a suture which has a suitable flexibility and high amenability to the correction of deformation such as the curl due to winding on a reel and is easy to handle and which further has an exceedingly high breaking strength.

To fulfill the above object, the present invention provides a surgical suture characterized in that the suture comprises a core of at least one synthetic fiber filament yarn and a covering layer formed of a plurality of silk strands and sheathing the core, the core and the covering layer having substantially the same elongation at break.

The core can be formed of a plurality of synthetic fiber filament yarns extending in parallel to one another and each having substantially the same elongation at break as the covering layer.

Furthermore, the core can be formed of single-twisted or plaited filament yarns of synthetic fiber and made to have substantially the same elongation at break as the covering layer.

Furthermore, the core can be formed by plaiting a plurality of synthetic fiber filament yarns and made to have substantially the same elongation at break as the covering layer.

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The covering layer can be formed by plaiting the plurality of silk strands and made to have substantially the same elongation at break as the core.

The synthetic fiber filament yarn can be made of any of various materials such as nylon, polyester, polypropylene and acrylic, among which polyester which has high breaking strength per denier is especially desirable from the viewpoint of giving improved strength to the suture.

The suture of the present invention has a suitable flexibility due to the rigidity of the core of synthetic fiber filament yarn and because of the flexibility of the covering layer of silk strands, and is thereby given high amenability to the correction of deformation such as the curl due to winding on reels and made easy to handle, hence outstanding advantages. The suture has another advantage; that it is readily deformable to a form suited to suturing during surgery. These great advantages appear attributable also to the fact that slippage occurs more smoothly between the synthetic fiber filament yarn core and the silk strand covering layer than between silk strands.

In the case of the suture already proposed (Japanese Utility Model Application No. 41670/1987) comprising a core of synthetic fiber filament yarn, the filament yarn generally has a higher elongation at break than the silk strands, so that when the suture is stretched under tension, the silk strands reach the limit of elongation (elongation at break) and break first. The force thereafter acts only on the filament yarn to break the yarn. Consequently, the overall breaking strength of the suture is lower than the sum of the individual breaking strengths of the yarn and the silk strands. According to the invention, on the other hand, the core of synthetic fiber filament yarn has substantially the same elongation at break as the covering layer of silk strands, with the result that when the suture breaks under tension, both the core and the covering layer break at the same time. Thus, the sum of the individual breaking strengths of the two is substantially equal to the overall breaking strength of the suture. In this case, synthetic fiber filaments increase in modulus of elasticity as they are made smaller in elongation at break by adjustment through thermal drawing. Accordingly, when the suture comprising such synthetic fiber filaments is compared with the suture comprising usual synthetic fiber filaments, the tensile force acting on the suture when the silk strands are stretched to break is greater on the former suture than on the latter by an amount corresponding to the increase in the modulus of elasticity. Thus, the former suture has a corresponding higher breaking strength. Moreover, the suture has further increased breaking strength because the synthetic fiber filament has higher breaking strength with a decrease in elongation at break. Because of the improved strength, sutures of small diameter are usable for wider application and are advantageous in avoiding injuries to the tissues of the human body to be sutured.

The reduction in the elongation at break gives somewhat increased rigidity to synthetic fiber filaments, makes them more suitable to use and is advantageous in facilitating correction of the deformation of the suture rendering the suture handleable with greater ease.

In the case where the core is formed of synthetic fiber filament yarns extending substantially parallel to one another, it is desirable that the filament yarns be at least 18% to not greater than 24%, more preferably at least 19% to not greater than 21%, in elongation at break

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because silk strands are generally 18 to 19% in elongation at break and exhibit an elongation at break of 18 to 24%, usually 19 to 21%, when formed into a covering layer by plaiting and so on.

When the core is prepared from synthetic fiber filament yarns by single twisting, plying or plaiting, the core thus formed is adapted to have the same elongation at break as the covering layer, and the elongation is suitably determined in view of twisting or plaiting density, strength, etc.

When the suture to be obtained has a relatively large size of USP2-0 or greater, it is especially desirable to form the core by plying the yarns so that the first twist and the final twist are in opposite directions to offset the torques due to the twists. For sutures of relatively small size of USP3-0 or smaller, single twisting achieves satisfactory results. Although the number of twists for the core is preferably greater to give improved breaking strength to the suture, the filament yarns may be loosely twisted with about 20 to about 50 T/m when made into a compacted ply.

To assure facilitated correction of deformation and improved breaking strength, it is desirable for the suture to have the core in a greater proportion as will become apparent from the following embodiments, especially from the results given in Table 1.

The present invention will become more apparent from the embodiments to be described below with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view partly broken away showing a suture embodying the invention;

FIG. 2 is a view in section taken along the line A—A in FIG. 1;

FIG. 3 is a perspective view showing a core of another embodiment; and

FIG. 4 is a graph showing the relationship between the load and the elongation, as determined for the suture of the invention and a conventional suture and involving a break.

DETAILED DESCRIPTION OF INVENTION

Embodiment 1

Silk strands were each prepared from two scoured silk yarns substantially of 27 denier (median of fineness values involving usual variations) by twisting the yarns

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yarns (product of Teijin Limited, T300s, 20 denier, composed of 6 filaments, 19% in elongation at break) in S direction at 200 T/m to obtain a twisted unit, and twisting three such twisted units together in Z direction at 137 T/m. The core thus obtained was about 20% in elongation at break. The core was then sheathed with a covering layer by arranging the two types of silk strands alternately on a braiding machine and plaiting the strands, 16 in total number, into a braid at a density of 26 stitches/cm, whereby a suture of USP1-0 in size was obtained. The covering layer formed was about 20% in elongation at break.

The structure of the suture obtained is shown in FIG. 1, in which indicated at 1 is the covering layer formed by plaiting the silk strands, and at 2 is in the core of plied polyester yarn.

The suture prepared in this way had a breaking strength of 2.92 kgf which was 11% higher than that of conventional sutures made of silk yarns only and having the same size. The suture had suitable flexibility (i.e. suitable stiffness), was highly amenable to deformation such as curling and can easily be handled free of trouble. Embodiment 2

A single twist yarn serving as a core 2' as shown in FIG. 3 was prepared from three polyester filament yarns (product of Toray Industries, Inc., S200, 20 denier, composed of 6 filaments, 19% in elongation at break) by twisting the yarns together in S direction at 200 T/m. The core obtained was about 19% in elongation at break. The core 2' was then sheathed with a covering layer which was formed in the same manner as in Embodiment 1 by plaiting twelve silk strands into a braid at a density of 29 stitches/cm, whereby a suture of USP4-0 in size was obtained. The covering layer was about 19% in elongation at break.

The suture thus obtained and having a small size also exhibited excellent characteristics like the suture of Embodiment 1.

Other Embodiments

Sutures of varying sizes were prepared in the same manner as above and tested in comparison with conventional sutures. The results are shown in Table 1, in which the sutures of USP1-0 and USP4-0 in size were made of materials different from those of Embodiments 1 and 2. Accordingly, these sutures were slightly different from the above sutures in the results achieved.

TABLE 1

USP size		2	1	1-0	2-0	3-0	4-0	5-0	6-0
Invention	Number of component strands of covering layer	16	16	16	16	12	12	8	6
	Core ratio (%)	47	33	33	33	20	20	11	14
	Elongation at break (%)	27.8	25.0	23.7	22.2	20.3	20.0	19.4	18.5
	Breaking strength (kgf)	4.05	3.88	2.92	2.27	1.48	0.95	0.58	0.30
	Flexibility (cm)	18.5	17.5	17.0	17.0	16.0	15.5	12.0	11.0
Prior Art A	Breaking strength (kgf)	5.68	3.76	2.86	2.18	1.41	0.91	0.54	0.28
	Number of component strands of covering layer	16	16	16	16	12	12	8	6
	Core ratio (%)	15	15	15	15	4	4	0	0
	Elongation at break (%)	29.9	27.1	25.2	23.8	22.4	21.8	20.2	19.1
	Breaking strength (kgf)	4.94	3.50	2.79	2.04	1.30	0.83	0.46	0.25
Prior Art B	Flexibility (cm)	16.0	15.0	15.5	15.0	14.0	11.5	9.5	8.0

together in S direction at about 300 T/m (s27 Naka/2). Silk strands of another type were also prepared each from two silk yarns, the same as those used above, by twisting the yarns together in Z direction at about 300 T/m (z27 Naka/2). A plied yarn serving as a core was prepared by twisting together eight polyester filament

With reference to Table 1, the core ratio is the ratio of the core to the entire suture in weight as expressed in percentage. The flexibility was determined according to the method of JIS L-1096A. Prior Art (prior-art suture)

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A was prepared in the same manner as the suture of the invention except that a usual polyester filament yarn (24% in elongation at break) was used as the core. Prior Art (prior-art suture) B had a silk yarn as the core.

The suture of the invention and a conventional suture comprising a core of usual synthetic fiber filament yarn, both USPI in size, were subjected to a tensile test. FIG. 4 is a graph showing the results. The graph reveals that the suture of the invention has exceedingly higher breaking strength (peak value). The graph also shows that with the conventional suture, the descending line representing a break has an intermediate peak, which indicate that the break involves a time lag between the core and the covering layer. With the suture of the invention, the descending line extends downward almost straight, indicating that the core and the covering layer broke at the same time.

When actually used for operations by surgeons, the sutures of the above embodiments were evaluated as being highly amenable to the correction of curls and like deformations, suitably flexible (suitably stiff), easy to handle to assure an efficient operation and free of any break during handling even when of a reduced size.

The suture of the invention is not limited to the foregoing embodiments but can be modified variously within the scope of the invention defined in the appended claims.

We claim:

1. A surgical suture characterized in that the suture comprises a core of at least one synthetic fiber filament yarn, and a covering layer formed of a plurality of silk strands and sheathing the core, the core and the cover-

6

ing layer having substantially the same elongation at break.

2. A suture as defined in claim 1 wherein the core is formed of a plurality of synthetic fiber filament yarns extending substantially in parallel to one another and each having substantially the same elongation at break as the covering layer.

3. A suture as defined in claim 2 wherein each of the filament yarns is at least 18% to not greater than 24% in elongation at break.

4. A suture as defined in claim 1 wherein the core is formed of a plurality of twisted synthetic fiber filament yarns and made to have substantially the same elongation at break as the covering layer.

5. A suture as defined in claim 4 wherein the synthetic fiber filament yarns are single-twisted.

6. A suture as defined in claim 4 wherein the synthetic fiber filament yarns are plied.

7. A suture as defined in claim 5 which is 9—0 to 3—0 in USP size.

8. A suture as defined in claim 6 which is 2—0 to 10 in USP size.

9. A suture as defined in claim 1 wherein the core is formed of a plurality of braided synthetic fiber filament yarns and made to have substantially the same elongation at break as the covering layer.

10. A suture as defined in claim 1 wherein the plurality of silk strands are braided to form the covering layer and made to have substantially the same elongation at break as the core.

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DePuy Mitek, Inc. v. Arthrex, Inc.

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(54) Improvements relating to fishing lines

(57) A fishing line of braided construction has some filaments of high tensile polythene. The other filaments are of polyester and/or nylon, and the braid may be coated with a sheath of polyurethane.

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"Improvements relating to Fishing Lines"

This invention relates to fishing lines.

Fishing lines require many qualities, such as high tensile strength, while having a small diameter, non-stretchability, resistance to abrasion, smooth running and suppleness. It is the aim of this invention to provide a line embodying most of these not usually very compatible properties.

According to the present invention there is provided a fishing line of braided construction, some braid filaments being of high tensile polythene thread and other filaments being of polyester and/or nylon.

The high tensile polythene gives the line minimal stretchability and will preferably be a high molecular weight polythene, melted in a solvent and drawn at high speed into extremely fine strands. This produces almost perfect alignment of all the molecules in long chains. A suitable product is that sold under the Registered Trade Mark DYNEEMA.

With polyester, multifilaments will generally be used, and the more there are of them in proportion to the polythene the stiffer the line will be. With nylon, monofilaments will preferably be used and the principal effect will be a low coefficient of friction.

-1-

-2-

It would be possible for certain applications to combine both polyester and nylon with the polythene thread.

The braid may be coated with a thin, supple
5 and smooth sheath of polyurethane and this may
be carried out by a simple immersion process in
liquid polyurethane. It will alter the
characteristics (such as buoyancy and strength)
in a predictable manner, but its main purpose is
10 to prevent saturation of the interstices of the
braid. In very cold conditions, such as fishing
through holes in ice, water having worked its
way into the braid will freeze and impart a
brittleness that can lead to breakage.

SL/SCS

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CLAIMS

1. A fishing line of braided construction,
some braid filaments being of high tenaxile polythene
thread and other filaments being of polyester and/or
nylon.

5 2. A line as claimed in Claim 1, wherein
the other filaments include polyester multi-filaments.

3. A line as claimed in Claim 1 or 2, wherein
the other filaments include nylon monofilaments.

4. A line as claimed in Claim 1, 2 or 3, wherein
10 the braid is coated by a sheath of polyurethane.

5. A line as claimed in any preceding Claim,
wherein the polythene is that sold under the Trade Mark
DYNEEMA.

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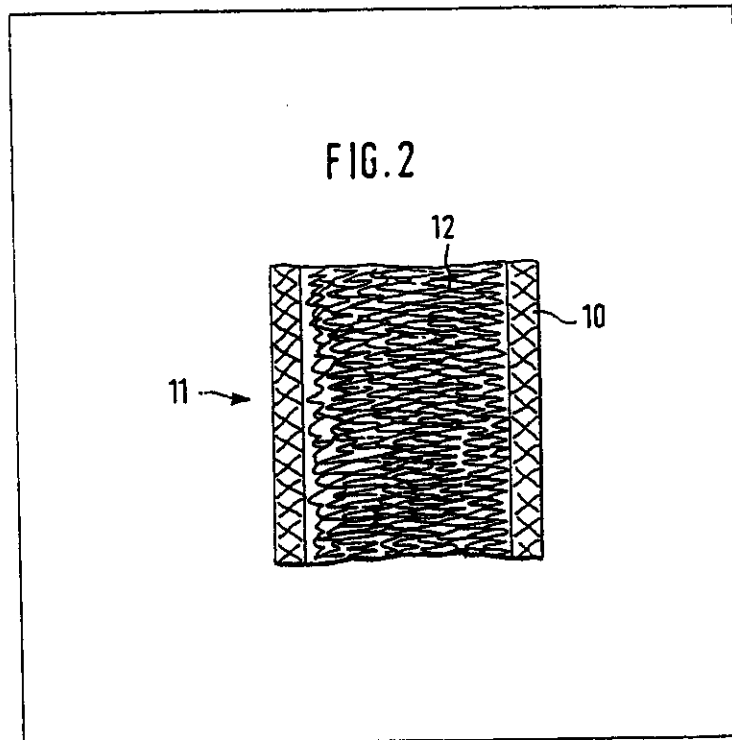
(54) Surgical stitching thread

(57) Surgical stitching thread, has a sheathing (10) in the form of a tubular braided structure, which is braided from a number of multifilament yarns, each of which consists of smooth

unrimped filaments. For reducing the surface roughness of the sheathing the number of bobbins is increased for the braiding process and the number of braids of the sheathing per axial length is reduced.

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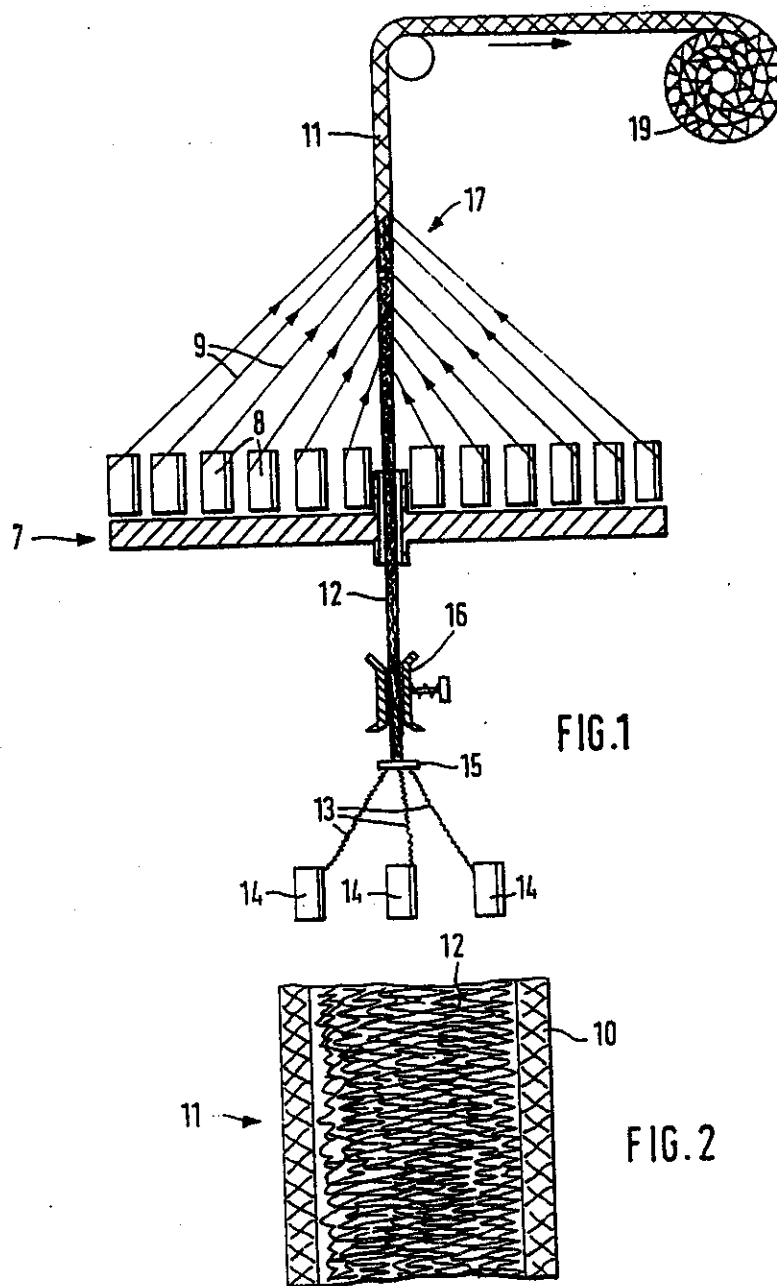
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SPECIFICATION
Surgical stitching thread

- The invention relates to surgical stitching thread having a tubular braided sheathing composed of a plurality of multi-filaments each of which consists of smooth uncrimped filaments.
- 5 Surgical stitching threads of this kind consist of the sheathing alone or of the sheathing and of a core round which this sheathing is wound. The multifilament yarns which are braided together to form the sheathing consists of synthetic plastics filaments which can decompose in the human body (e.g. polyglycolic acid) or synthetic plastics filaments which cannot decompose in the human body (e.g. polyester, polyamide, polypropylene) and/or metal filaments. Filaments of the same materials as for the
- 10 hitherto known surgical stitching thread can be used for the stitching thread according to the invention. However, filaments from other materials may possibly be considered, in particular materials which are used in the production of synthetic fibres. By "filament" is meant an elongate structure such as can be formed, in the case of synthetic plastics materials, viscose or the like, by means of a hole of a spinning nozzle (spinnaret) or multiple spinning nozzle and, in the case of metal, by means of a hole of a drawing
- 15 die of a drawing tool. Filaments of synthetic plastics material, viscose or the like are also referred to as endless chemical fibres, elementary fibres or capillaries.
- By the hereinafter used term "braid number Z" is meant the number of braids present on a generatrix (also called "edge"), extending axially parallel to the longitudinal axis of the stitching thread, per French inch (equals 27.07 mm).
- 20 The following symbols and expressions are used hereinafter:
- Z = The number of braids in accordance with the above definition.
K = the number of bobbins (number of bobbins which — in the course of braiding the sheathing — delivered the multi-filament yarns (braiding yarns) which form the multi-filament yarns).
Multifilament yarn = a yarn in the form of a number of filaments.
GT = the count (titre) of the individual yarn, also referred to hereinafter as "individual count", in
- 25 dtex.
- N = the number of yarns of which the core consists.
F = the number of filaments of a multifilament yarn
USP-size = diameter ranges of surgical stitching threads in accordance with United States Pharmacopeiae XIX, pages 486, 665, Pharma Copiae Convention Inc. Meeting at Washington D.C. April 1970, 12601 Twinbrook, USA.
- 30 The tubular braided structures of such surgical stitching threads have hitherto been formed with a large number of braids and, in comparison with this a small number of bobbins, and the multifilament yarns which are braided together each had a relatively large individual count (titre); the filaments of the individual yarns also had a relatively large count or titre. Table 1 appended to the end of the specification contains the combinations of values, pertinent to this, of the surgical stitching threads used up to the present time.
- 35 Insofar as these known surgical stitching threads had a so-called core, the latter consisted of a ply yarn, which was formed from a number of filament yarns by twisting the latter round one another; the filaments of this ply yarn were uncrimped.
- 40 The sheathing forming the outside surface of the surgical stitching thread has relatively high roughness in the case of the numbers of bobbins and numbers of braids which have hitherto been conventional. The result of this, when stitching human or animal tissue by means of these known surgical stitching threads, has been that the stitching threads can cut into the tissue, in the manner of a saw, and thus enlarge the wounds, and delay the healing process. Also, this rough sheathing increases
- 45 the force required for pulling the surgical stitching thread through the tissue, which makes it more difficult to perform the stitching operation in a sensitive manner.
- It is therefore an object of the invention to provide a surgical stitching thread of the type defined at the outset, the outside surface of whose sheathing can be made with lower surface roughness than the surgical stitching threads, made from the same base material, of the same USP size according to Table
- 50 1.
- According to the invention therefore for the purpose of reducing the surface roughness of the sheathing — the number of bobbins, when braiding the sheathing, in comparison with the known surgical stitching threads, specified in Table 1 of the same diameter range (USP size) is increased, whilst
- 55 the number of braids of the sheathing in comparison with these known surgical stitching threads is decreased.
- To increase the number of bobbins and reduce the number of braids, the outside surface of the surgical stitching thread becomes smoother, that is to say it becomes less rough than is the case with the hitherto conventional stitching threads made from the same basic material and of the same USP size as set forth in Table 1. Consequently, it is possible to pull these surgical stitching threads through
- 60 human or animal tissue with less force, so that the surgeon can stitch with more sensitivity than hitherto. Also, the human or animal tissue is damaged to a lesser extent by these surgical stitching threads, and so the healing process of the wound is also facilitated.
- The individual counts (titres) GT of the yarns of the sheathing of the stitching thread according to

the invention are, due to the increased number of bobbins, smaller than those of the known stitching threads of the same USP size as set out in Table 1.

The material of the filaments of the sheathing of the surgical stitching thread may consist of the materials which have already been referred to above, preferably of synthetic plastics materials, for example polyester, polypropylene, polyglycolic acid or also of other suitable materials, such as for example viscose silk, natural silk, metal or the like.

The diameter of the surgical stitching threads according to the invention is, in particular, within the range of USP sizes 7—0 to 6. It will be appropriate if the stitching threads are without a core within the USP size range 7—0 and 6—0, and if the stitching threads comprise a core within the size range 4—0 to 6. In the intermediate range of USP sizes 5—0 and 4—0 it will preferably be optional whether the stitching threads contain a core or not.

If the stitching thread according to the invention contains a core, the structure and material of its filaments may be conventional, that is to say these filaments will consist of a ply yarn or of an individual yarn. However, in accordance with a modification of the invention, the core may consist of doubled (folded) multifilament yarns, that is to say these multifilament yarns extend parallel to the longitudinal axis of the stitching thread and are not twisted round one another, that is to say they do not form a ply yarn. Also, in the case of the known surgical stitching threads having a core, the filaments of the core were always uncrimped. This may also be the case with the surgical stitching threads according to the invention. However, in accordance with a modification of the invention, at least some, and preferably all, filaments of the core are crimped, as in this way the surgical stitching thread may be made more pliant, so that its stitching performance and compatibility can be further improved.

Generally speaking, it will be satisfactory if the core consists of one or more multifilament yarns. However, in special cases, the core may consist of a single monofilament or of a number of filaments (viz. monofilaments) which are not twisted round one another, that is to say they are doubled (folded). Conveniently, with a view to ensuring that, in this case, the stitching thread has good qualities of pliability and circularity, the monofilament or monofilaments may consist of elastomeric material, preferably of silicone rubber or elastomeric polyurethane.

Preferred bobbin numbers K and braid numbers Z of the tubular sheathing of the surgical stitching threads according to the invention are specified in claims 2 to 13. The surgical stitching threads specified in claims 14 to 25 result, in practice, in optimally smooth surfaces allied to good qualities of pliability and to other favourable properties of the stitching thread.

The yarns (braiding yarns) used for braiding the sheathing of the surgical stitching thread have, in consequence of the higher bobbin numbers and of the lower braid numbers used for the braiding process, smaller individual counts GT than in the case of the hitherto conventional surgical stitching thread set out in Table 1. Multifilament yarns with the highest possible number of filaments have been found to be particularly favourable for braiding the sheathing of the stitching thread according to the invention.

In Table 2, appearing at the end of the specification, preferred structural data are given for a number of surgical stitching threads constituted in accordance with the invention; the numbers K of bobbins and numbers Z of braids in accordance with the preferred embodiments as specified in Claims 14 to 25 appear in this table. The individual counts GT, given in Claims 26 to 29 and in Table 2, of the multifilament yarns forming the sheathings and cores are particularly favourable; similarly, the other structural data given for these surgical stitching threads are also particularly favourable.

Normally, when the sheathing is being formed by braiding, one multifilament yarn runs from each bobbin of the braiding machine concerned to the braiding point. However, it is also possible, in the case of the surgical stitching thread according to the invention — and this may lead to a still more smooth surface of the stitching thread — to arrange for a number of multifilament yarns to run, in doubled (folded) fashion, to the braiding point, from at least one of the bobbins, preferably from all of the bobbins, so that the sheathing will be braided from a correspondingly greater number of multifilament yarns. As has already been mentioned, the multifilament yarns of the sheathing are uncrimped.

The smooth outer surface of the surgical stitching thread according to the invention is formed by the outside surface of the sheathing, which has been formed by braiding. Moreover, in special instances, provision may be made for providing the outside surface of the sheathing with preparations or the like for achieving special properties.

Further, it will be feasible in special instances, to replace at least one multifilament yarn of the sheathing by a monofilament or by a number of doubled (folded) filaments, that is to say filaments which about one another in parallel fashion and are not twisted onto one another.

Embodiments of the invention are illustrated in the drawing, in which:

Figure 1 schematically represents a braiding machine for producing a surgical stitching thread constituted according to the invention, and

Figure 2 is a longitudinal cross-section taken through part of a surgical stitching thread in accordance with one embodiment of the invention; this stitching thread section is represented on a greatly enlarged scale.

The braiding machine 7 shown in Figure 1 comprises twelve bobbins 8, viz. yarn bobbins on which non-crimped multifilament yarns 9 are wound, these yarns 9 being braided so as to form the sheathing

10 (Figure 2) of a surgical stitching thread 11 to be produced on this braiding machine. The core 12 of this stitching thread, to be formed by braiding, consists of a number of doubled (folded) yarns 13 which, in this embodiment, are crimped multifilament yarns and are drawn off from bobbins 14 and commonly run to a yarn guide 15, pass through a thread brake 16, which is biased in a variable fashion, whence the yarns 13 pass to the braiding point 17, at which they are enveloped by the braiding yarns 9, that is to say the sheathing 10, which envelopes the core 12, are braided from the braiding yarn 9. The production of this surgical stitching thread takes place continuously, and is wound up into a thread package 19. 5

The short portion, shown in longitudinal cross-section in Figure 2 of an embodiment of a stitching thread 11 according to the invention has a substantially cylindrical sheathing 10 consisting of a tubular braided structure, in the interior of which lies a core 12 which consists of a number of crimped multifilament yarns which extend axially in the sheathing. 10

The free circumferential surface of this surgical stitching thread is preferably solely constituted by the multifilament yarns of the sheathing. However, it is also possible to provide this sheathing with a finish, which for example has an anti-bacterial action or imparts other desired properties to the stitching thread. 15

The individual multifilament yarns of the sheathings and cores of the known stitching threads set out in Table 1 have so-called protective twists, that is to say a small degree of twist (e.g. 10 to 130 turns/meter, according to the individual count or titre in each instance). Conveniently, this may also be the case with the surgical stitching thread according to the invention. In accordance with a modification of the invention somewhat better smoothness of the surface of the sheathing can be achieved by making the multifilament yarns of the sheathing twist free, that is to say they have no twist at all. If the core has one or more multifilament yarns, this provision may also be made for these yarns. 20

TABLE 1

5107	sheathing braided from uncrimped multi-filament yams			core from non-crimped multi-filament yams
USP-Size	K	Z	Game	N x GT, f GT in dtex
7-0	4	42 to 53	GT 35, f 15 GT 15, f 10	—
6-0	4 to 6	42 to 50	GT 35, f 15 GT 15, f 10	—
5-0	4 to 8	50 to 80	GT 35, f 15 GT 30, f 20	—
4-0	8	59 to 65	GT 49, f 16 GT 78, f 24	—
3-0	8	58 to 68	GT 95, f 24 GT 76, f 24	1 x GT 150, f 24
2-0	6 to 8	50 to 61	GT 190, f 48 GT 76, f 24	2 x GT 80, f 20 (ply yam)
0	8 to 12	55 to 60	GT 190, f 48 GT 111, f 32	—
1	12 to 16	53 to 67	GT 190, f 48 GT 111, f 32	1 x GT 226, f 64 2 x GT 74, f 18 (ply yam)
2	12 to 16	50 to 67	GT 280, f 72 GT 111, f 32	2 x GT 76, f 18 (ply yam) 1 x GT 308, f 108
3 and 4	12	50 to 65	GT 280, f 72 GT 280, f 50	3 x GT 180, f 24 (ply yam) 1 x GT 280, f 50
5	12 to 16	52 to 70	GT 380, f 72 GT 340, f 80	5 x GT 180, f 24 (ply yam) 3 x GT 455, f 96 (ply yam)
6	12 to 16	52 to 70	GT 380, f 96 GT 390, f 66	6 x GT 180, f 24 (ply yam) 3 x GT 660, f 20 (ply yam)

TABLE 2

5107 USP-Size	sheathing braided from uncrimped multi-filament yarns				core from doubled (folded), crimped multi-filament yarns		
	K	GT (dtex)	f	Z	N	GT (dtex)	f
7-0	8	25	22	8			
6-0	8	25	22	13			
5-0	12	25	22	18			
4-0	12	25	22	20	3	50	24
3-0	12	49	16	18	3	50	24
2-0	16	49	16	23	6	50	24
0	16 or 24	49	16	25	8	50	24
1	18 or 24	49	16	21 or 27	10 or 12	50	24
2	24	49	16	27	12	50	24
3 and 4	20	113	32	25	20	50	24
5	20	113	32	21	30	50	24
6	24	113	32	19	35	50	24
2	18	113	32	21	12	50	24
3 and 4	24	95	24	19	20	50	24
5	24	95	24	19	25	50	24

CLAIMS

1. Surgical stitching thread having a tubular braided sheathing composed of a plurality of multifilament yarns, each of which consists of smooth uncrimped filaments, characterised in that, for reducing the surface roughness of the sheathing, the number of bobbins (K) used for braiding the sheathing is increased in comparison with the known surgical stitching threads, specified in aforesaid Table 1, of the same diameter range (USP-size), and the number of braids (Z) in the sheathing is reduced in comparison with these known surgical stitching threads.
2. Surgical stitching thread of USP-size 7—0 according to claim 1, having its sheathing braided with a number of bobbins K equal to 6, 8 or 10, and with a number of braids Z equal to 8 to 15, in which K is the number of bobbins used for braiding the sheathing and Z is the number of braids per French inch.
3. Surgical stitching thread of USP-size 6—0, according to claim 1, having its sheathing braided with K equal to 8 or 10 and with Z equal to 10 to 20.
4. Surgical stitching thread of USP-size 5—0, according to claim 1, having its sheathing braided with K equal to 10 or 12, and with Z equal to 10 to 20.
5. Surgical stitching thread of USP-size 4—0, according to claim 1, having its sheathing braided with K equal to 10, 12 or 14, and with Z equal to 15 to 25.
6. Surgical stitching thread of USP-size 3—0, according to claim 1, having its sheathing braided with K equal to 10, 12 or 14, and with Z equal to 15 to 25.
7. Surgical stitching thread of USP-size 2—0, according to claim 1, having its sheathing braided with K equal to 12, 14 or 16, and with Z equal to 17 to 27.
8. Surgical stitching thread of USP-size 0, according to claim 1, having its sheathing braided with K equal to 14, 16, 18, 20 or 24, and with Z equal to 17 to 27.
9. Surgical stitching thread of USP-size 1, according to claim 1, having its sheathing braided with

- K equal to 18, 20 or 24 and with Z equal to 17 to 27.
10. Surgical stitching thread of USP-size 2, according to claim 1, having its sheathing braided with K equal to 18, 20, 22, 24 or 26, and with Z equal to 17 to 30.
11. Surgical stitching thread of USP-size 3 and 4, according to claim 1, having its sheathing
5 braided with K equal to 18, 10, 22, 24, 26 and with Z equal to 17 to 30.
12. Surgical stitching thread of USP-size 5, according to claim 1, having its sheathing braided with K equal to 18, 20, 22, 24 or 26, and with Z equal to 17 to 30.
13. Surgical stitching thread of USP-size 6, according to claim 1, having its sheathing braided with K equal to 20, 22, 24 or 26, and with Z equal to 17 to 30.
- 10 14. Surgical stitching thread according to claim 2, having its sheathing braided with K equal to 8, and with Z equal to 8.
15. Surgical stitching thread according to claim 3, having its sheathing braided with K equal to 8 and with Z equal to 13.
16. Surgical stitching thread according to claim 4, having its sheathing braided with K equal to 12
15 and Z equal to 18.
17. Surgical stitching thread according to claim 5, having its sheathing braided with K equal to 12 and Z equal to 20.
18. Surgical stitching thread according to claim 6, having its sheathing braided with K equal to 12 and with Z equal to 18.
- 20 19. Surgical stitching thread according to claim 7, having its sheathing braided with K equal to 16 and with Z equal to 23.
20. Surgical stitching thread according to claim 8, having its sheathing braided with K equal to 16 or 24, and with Z equal to 25.
21. Surgical stitching thread according to claim 9, having its sheathing braided with K equal to 18
25 or 24, and with Z equal to 21 or 27.
22. Surgical stitching thread according to claim 10, having its sheathing braided with K equal to 24 and with Z equal to 27.
23. Surgical stitching thread according to claim 11, having its sheathing braided with K equal to 20 or 24, and with Z equal to 19 or 27.
- 30 24. Surgical stitching thread according to claim 12, having its sheathing braided with K equal to 20 or 24, and with Z equal to 19 or 21.
25. Surgical stitching thread according to claim 13, having its sheathing braided with K equal to 24 and with Z equal to 19.
26. Surgical stitching thread according to any of claims 2 to 5 or 14 to 17, having its sheathing
35 braided from multifilament yarns, each of which has an individual count (titre) of 20 to 30 dtex, preferably of about 25 dtex, and preferably at least 22 filaments.
27. Surgical stitching thread according to any of claims 6 to 10 or 18 to 22, having its sheathing
braided from multifilament yarns, each of which has an individual count of 40 to 60 dtex, preferably of about 49 dtex, and preferably at least 16 filaments.
- 40 28. Surgical stitching thread according to any of claims 11 to 13 or 23 to 25, having its sheathing braided from multifilament yarns, each of which has an individual count of 80 to 120 dtex, preferably 113 dtex, and preferably at least 32 filaments.
29. Surgical stitching thread according to claim 9 or claim 21, having its sheathing braided from
45 multifilament yarns, each of which has an individual count of 60 to 90 dtex, preferably of about 74 dtex, and preferably at least 24 filaments.
30. Surgical stitching thread according to any of the foregoing claims, having at least one filament
of its sheathing, and preferably all filaments of its sheathing, made of synthetic plastics material.
31. Surgical stitching thread according to any of the foregoing claims, having at least one filament
50 of its sheathing, and preferably all of its filaments, made of metal.
32. Surgical stitching thread according to any of the foregoing claims, having at least one filament
of its sheathing, and preferably all of its filaments, made of viscose or polyglycolic acid.
33. Surgical stitching thread according to any of the foregoing claims, having at least one filament
yarn of its sheathing made of natural silk.
34. Surgical stitching thread according to claim 1, having a USP size of from 7—0 to 3—0, and
55 which exclusively consists of the sheathing.
35. Surgical stitching thread according to claim 1, having a USP size of from 4—0 to 6, and in
which a core is arranged within its sheathing.
36. Surgical stitching thread according to claim 35, in which its core comprises at least one
multifilament yarn, preferably in the form of synthetic plastics material filaments.
- 60 37. Surgical stitching thread according to claim 35, having a core which consists of one or more monofilaments which extend parallel to the longitudinal axis of the surgical stitching thread and are of elastomeric material, preferably silicone-rubber or polyurethane.
38. Surgical stitching thread according to claim 36, having a core which consists of a plurality of
multifilament yarns which are braided so as to form a tube.
- 65 39. Surgical stitching thread according to claim 36, in which its core consists of a plurality of

folded (doubled) multifilament yarns.

40. Surgical stitching thread according to any of claims 36 to 39, in which the filaments of its core are uncrimped.

41. Surgical stitching thread according to any of claims 36 to 39, in which at least one filament of its core, and preferably all of its filaments, are crimped. 5

42. Surgical stitching thread according to any of the foregoing claims, in which the number of multifilament yarns of which the sheathing consists, corresponds to the number K of bobbins used for braiding the sheathing.

43. Surgical stitching thread according to any of claims 1 to 41, wherein the number of multifilament yarns, of which the sheathing consists, is greater than the number K of bobbins used for braiding the sheathing, this being accomplished by arranging that, when the sheathing is being braided, from at least one bobbin at least two multifilament yarns are guided, doubled (folded) and parallel to one another, to the braiding point. 10

44. Surgical stitching thread according to any of the foregoing claims, and of which its free outer surface is solely constituted by the multifilament yarns of the sheathing. 15

45. Surgical stitching thread according to any of claims 1 to 25 or 30 to 44, in which a monofilament or a number of doubled (folded) filaments, which are not twisted round one another, replace at least one multifilament yarn of the sheathing.

46. Surgical stitching thread according to any of the foregoing claims, in which the multifilament yarns of the sheathing and/or of the core have a small twist (so-called protective twist). 20

47. Surgical stitching thread according to any of claims 1 to 45, in which the multifilament yarns of the sheathing and/or of the core are twist free (without twist).

48. Surgical stitching thread composed substantially as hereinbefore described by reference to the accompanying Tables 1 and 2 and the drawing.

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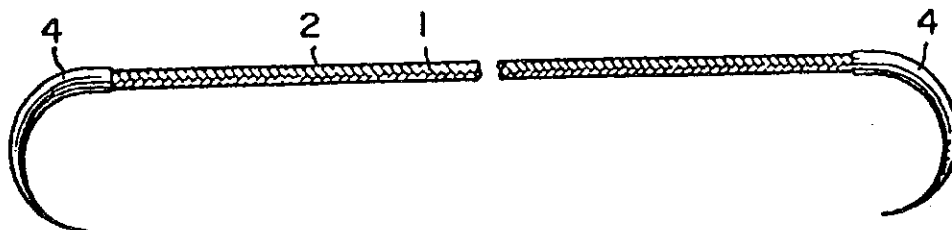
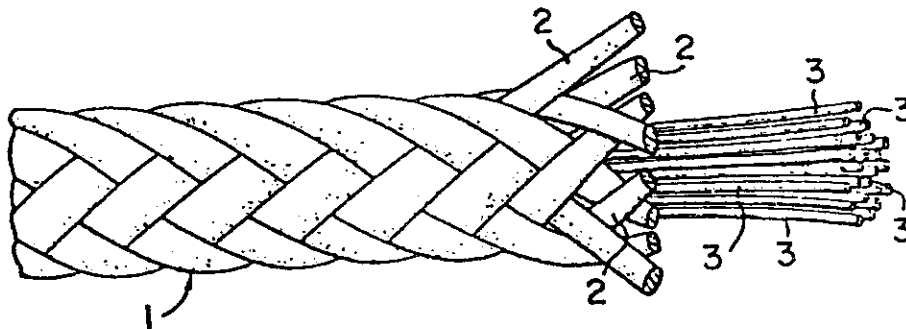
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Could you provide
a translation of summary please*

Subject: GERMAN PATENT APPLICATION 29 49 920 AND
"MATSUDA MEDICAL"

The claims for this application are as follows:

1. A surgical suture characterized by the fact that it consists of a tubular weave (1) of fine synthetic fibers (2) surrounding fine platinum fibers or pure gold fibers (3) swaged to at least one surgical needle (4).
2. A surgical suture characterized by the fact that the fine synthetic fibers (2) which form the woven (braided) tube (1) consist of polytetrafluoroethylene fibers.



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C.A. No.04-12457 PBS
DMI000135

C. G. FRITZ, Ph.D.

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FIG. 1

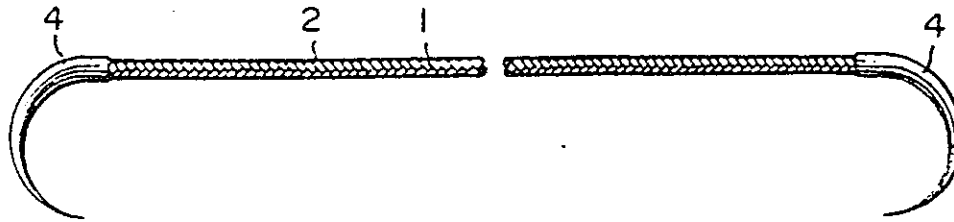


FIG. 2

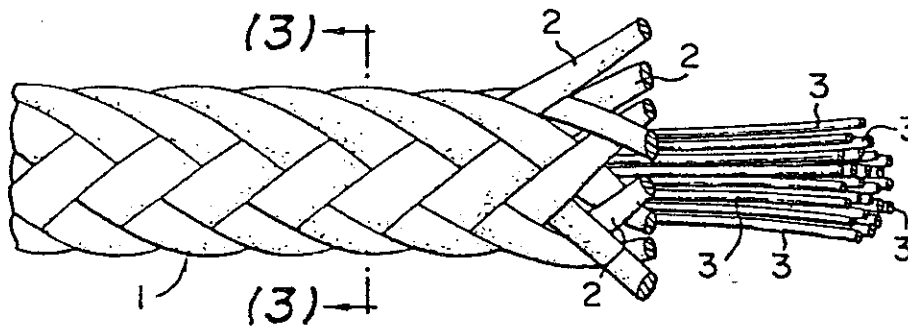
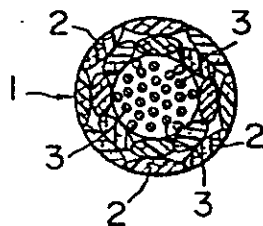


FIG. 3



130012/0575

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Chirurgisches Nahtmaterial

P A T E N T A N S P R Ü C H E

1. Chirurgisches Nahtmaterial, gekennzeichnet durch ein rohrförmiges Geflecht (1) aus sehr dünnen zusammengeflochtenen chemischen Faserfäden (2), durch eine Anzahl von sehr dünnen Platinfäden oder reinen Goldfäden (3), die in das rohrförmige Geflecht (1) über dessen gesamte Länge eingesetzt sind, und durch wenigstens eine chirurgische Nadel (4), die in einem Stück mit einem Ende des rohrförmigen Geflechts (1) verbunden ist.

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2. Chirurgisches Nahtmaterial nach Anspruch 1, dadurch gekennzeichnet, dass die sehr dünnen chemischen Faserfäden (2), die das rohrförmige Geflecht (1) bilden, Polytetrafluoräthylen-Faserfäden sind.

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Beschreibung

Die Erfindung betrifft ein chirurgisches Nahtmaterial.

Als Nahtmaterialien für chirurgische Eingriffe werden bisher in üblicher Weise Materialien aus tierischen Fasern, beispielsweise aus Seide, verwandt. Diese Nahtmaterialien aus tierischen Fasern rufen jedoch eine Reibung mit den inneren Organen bei Bauchoperationen hervor und bringen die Gefahr mit sich, dass die verschiedenen Funktionen der Organe beeinträchtigt werden, was manchmal zu einer Abstossung führt.

Nach der Operation kann darüberhinaus das Nahtmaterial selbst einen Kapillareffekt bewirken. Wenn weiterhin ein künstliches Organ und ein natürliches Organ verbunden werden, besteht die Gefahr, dass das Nahtmaterial selbst mit dem natürlichen Organ verwächst und dessen normale Funktion behindert. Wenn weiterhin eine Infektion auftritt, ist es bisher mit dem Nahtmaterial aus tierischen Fasern unmöglich, die Organfunktion wieder herzustellen, bis das Nahtmaterial entfernt oder körperlich abgestossen ist.

Mit Nahtmaterialien aus Seide oder einem ähnlichen Material war es weiterhin bisher unmöglich, röntgenologisch, die miteinander vernähten Teile nach der Operation zu beobachten, so dass es schwierig war, die Funktion des Organs des Körpers nach der Operation zu verfolgen und zu analysieren.

Aufgabe der Erfindung ist daher die Entwicklung eines chirurgischen Nahtmaterials, das die oben beschriebenen Nachteile der bekannten Nahtmaterialien nicht aufweist, d.h. das kein Blut oder andere Körperfluide, Bakterien

usw. überträgt und somit keinen Kapillareffekt zeigt, und das ohne jede besondere Behandlung bei einer chirurgischen Operation einsatzbereit ist.

Diese Aufgabe wird erfindungsgemäss durch ein chirurgisches Nahtmaterial gelöst, das ein rohrförmiges Geflecht aus sehr dünnen zusammengeflochtenen chemischen Faserfäden, eine Anzahl von sehr dünnen Platinfäden oder reinen Goldfäden, die in das rohrförmige Geflecht über dessen gesamte Länge eingessetzt sind, und wenigstens eine chirurgische Nadel aufweist, die in einem Stück mit einem Ende des rohrförmigen Geflechtes verbunden ist.

Ein besonders bevorzugtes Ausführungsbeispiel des erfindungsgemässen chirurgischen Nahtmaterials zeichnet sich dadurch aus, dass die miteinander vernähten Teile des Körpers nach der Operation röntgenologisch beobachtet werden können, so dass die Funktion des Organs des Körpers nach der Operation verfolgt und analysiert werden kann.

Im folgenden wird anhand der zugehörigen Zeichnung ein bevorzugtes Ausführungsbeispiel der Erfindung näher erläutert:

Fig. 1 zeigt eine teilweise weggebrochene Seitenansicht des Ausführungsbeispiels des erfindungsgemässen Nahtmaterials.

Fig. 2 zeigt eine vergrösserte Teilvorderansicht des Ausführungsbeispiels des erfindungsgemässen Nahtmaterials, wobei die inneren Metallfäden teilweise durch Abschneiden und Weglassen des äusseren Geflechtes freigelegt sind.

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Fig. 3 zeigt eine Schnittansicht längs der Linie 3-3 in Fig. 2.

Wie es in der Zeichnung dargestellt ist, weist das Ausführungsbeispiel des erfindungsgemässen Nahtmaterials ein rohrförmiges Geflecht 1 auf, das aus sehr dünnen zusammengeflochtenen chemischen Faserfäden 2 besteht. Eine Anzahl von sehr dünnen Platinfäden oder reinen Goldfäden 3 ist in das rohrförmige Geflecht 1 über dessen gesamte Länge eingesetzt. Eine chirurgische Nadel 4 ist in einem Stück mit beiden Enden jeweils oder mit einem Ende des rohrförmigen Geflechtes 1 verbunden, das die Platinfäden oder die reinen Goldfäden 3 umschliesst, die in das Geflecht 1 eingesetzt sind.

Als Faserfäden 2, die das rohrförmige Geflecht 1 bilden, können solche Faserfäden, die eine glatte Oberfläche und eine hohe Dauerhaftigkeit, Abriebfestigkeit, Biegefestigkeit und Zugfestigkeit haben, beispielsweise Polyfluoräthylen-Faserfäden oder Polyester-Faserfäden, verwandt werden.

Das rohrförmige Geflecht 1 ist dadurch gebildet, dass eine Anzahl von Faserfäden 2 mit einer längenbezogenen Masse von $1/9 \cdot 10^2$ tex zusammengeflochten sind, wobei bei dem in den Fig. 2 und 3 dargestellten Ausführungsbeispiel 16 Fäden verwandt sind.

Die sehr dünnen Platinfäden oder die sehr dünnen reinen Goldfäden 3, die in das rohrförmige Geflecht 1 eingesetzt sind, haben eine Stärke von etwa 50 µm im Durchmesser, wobei etwa 20 derartige Fäden verwandt werden. Diese Platinfäden oder diese reinen Goldfäden 3 haben keinen Einfluss auf die

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inneren Organe, wenn sie sich im Körper befinden.

Die chirurgische Nadel 4 besteht aus rostfreiem Stahl oder einem Spezialstahl.

Mit Hilfe des oben beschriebenen Nahtmaterials kann das Ausführen der Naht reibungslos erfolgen, ohne die inneren Organe unnötigerweise zu verletzen, da die Fäden 2, aus denen das Geflecht 1 besteht, glatte Oberflächen haben. Aufgrund der Art seines Materials überträgt das Nahtmaterial darüberhinaus kein Blut oder andere Körperfluide aufgrund des Kapillareffektes. Ohne jede besondere Behandlung des Nahtmaterials können daher ein Anhaften und Fortpflanzen von Bakterien verhindert werden und können selbst dann, wenn Bakterien übertragen werden, die infizierten Bereiche leicht ausgeheilt werden.

Nach dem chirurgischen Eingriff können weiterhin röntgenologische Beobachtungen der Gewebebildung des lebenden Körpers und der Ergebnisse einer Langzeitgewebebildung nach der postoperativen Behandlung, beispielsweise der Nahtbildung, erfolgen und ist es gleichfalls möglich, fortlaufend Änderungen im Zustand des Operationsbereiches mit dessen Wanderung und andere bisher unbekannte Funktionen der Organe des Körpers auf Röntgenfilmen zu beobachten, was für die medizinische Behandlung ausserordentlich nützlich ist.

Das erfindungsgemässe chirurgische Nahtmaterial ist somit am besten für den chirurgischen Einsatz künstlicher Organe geeignet.

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FIG. 1

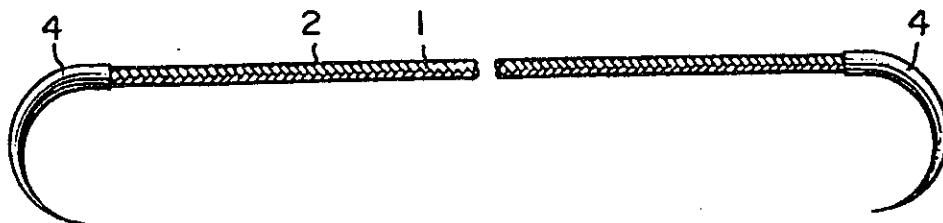


FIG. 2

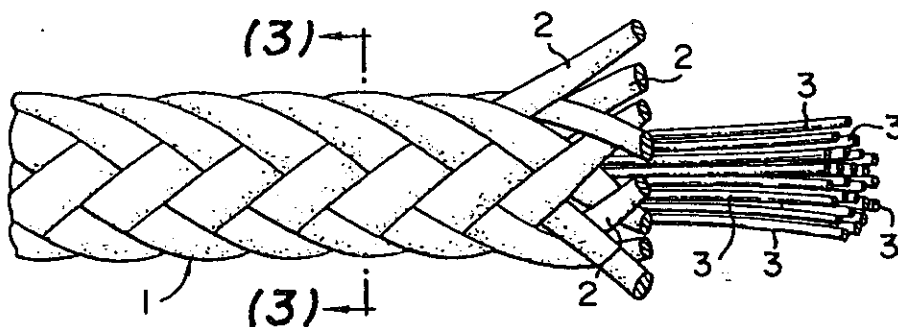
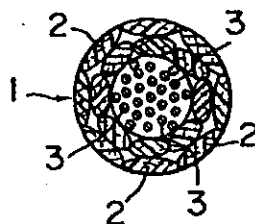


FIG. 3



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Representative:
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Subject: German Patent Application 29 49 920 and
"Matsuda Medical"

The claims for this application are as follows:

1. A surgical suture characterized by the fact that it consists of a tubular weave (1) of fine synthetic fibers or pure gold fibers (3) swaged to at least one surgical needle (4).
2. A surgical suture characterized by the fact that the fine synthetic fibers (2) which form the woven (braided) tube (1) consist of polytetrafluoroethylene fibers.

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Juro Wada, Tokyo, Japan

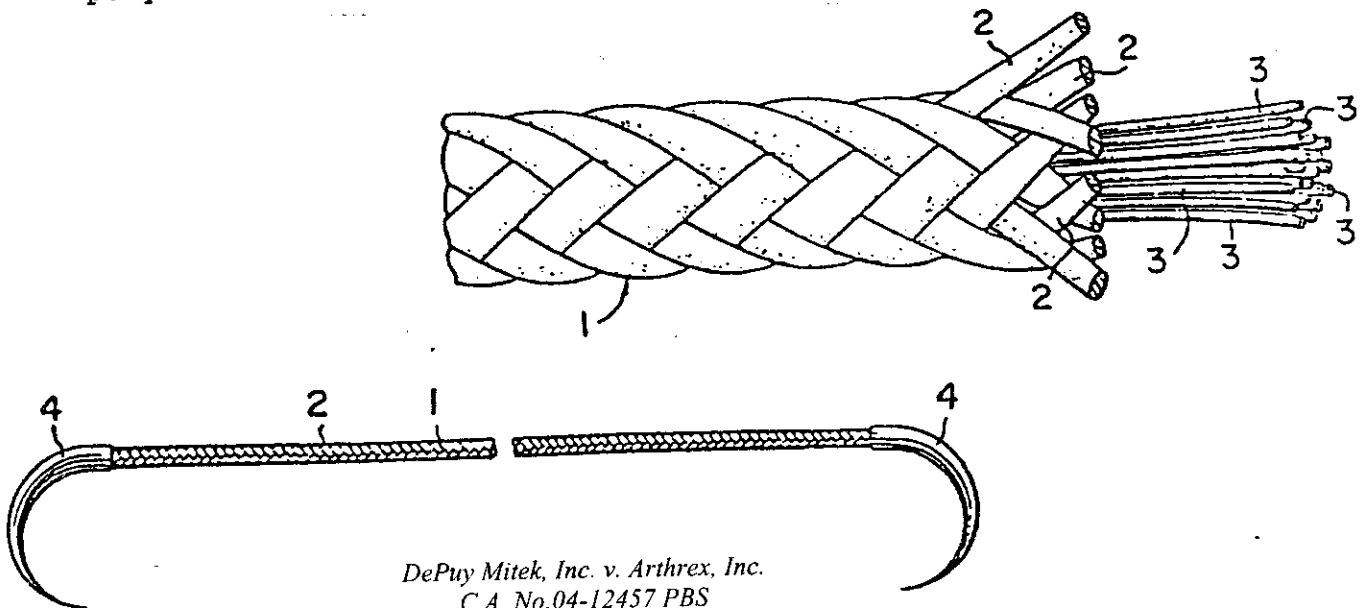
Kabushiki Kaisha Matsuda Ika Kogyo, Tokyo, Japan

SURGICAL SUTURE MATERIAL

PATENT CLAIMS

1. Surgical suture material characterized by a tubular braid (1) made of very thin synthetic fibers braided together (2), by a number of very thin platinum fibers or pure gold fibers (3) that are inserted into the tubular braid (1) over its entire length, and by at least one surgical needle (4) which is joined integrally to one end of the tubular braid (1).

2. Surgical suture material according to Claim 1, characterized by the fact that the very thin synthetic fibers (2) that form the tubular braid (1) are polytetrafluoroethylene fibers.



Description

The invention relates to a surgical suture material.

Up to now, materials made from animal fibers, for example silk, have commonly been used as suture materials for surgical operations. These suture materials made of animal fibers, however, cause friction with the internal organs during abdominal operations and are accompanied by a danger that the various functions of the organs will be impaired, which sometimes leads to rejection.

In addition, after the operation, the suture material itself can have a capillary effect. Further, when an artificial organ and a natural organ are joined there is a danger that the suture material itself will be overgrown by the natural organ and hinder its normal functioning. Moreover, when an infection occurs, it has up to now been impossible with animal fiber sutures to restore the organ function until the suture material is removed or physically rejected.

Further, with suture materials made of silk or a similar material, radiological observation of the parts sutured together has been impossible after the operation, so that it has been difficult to observe and analyse the functioning of the body organ after the operation.

The objective of the invention is therefore the development of a surgical suture material that does not have the above-described disadvantages of common suture materials, that is, which does not transport any blood or other body fluids, bacteria, etc., and thus does not display any capillary effect, and that is ready for use in a surgical operation without any special treatment.

This objective is achieved according to the invention by a surgical suture material that has a tubular braid made of very thin synthetic fibers braided together, a number of very thin platinum fibers or pure gold fibers which are inserted into the tubular braid over its entire length, and at least one surgical needle that is joined integrally to one end of the tubular braid.

A particularly preferred example of a realization of the surgical suture material of the invention is characterized by the fact that the parts of the body sutured together can be observed radiologically after the operation, so that the functioning of the body organ can be observed and analysed after the operation.

A preferred realization of the invention is described in more detail below with the aid of the accompanying drawings:

Fig. 1 shows a partially cut away lateral view of the realization of the suture material of the invention..

Fig. 2 shows a magnified partial frontal view of the realization of the suture material of the invention, with the inner metal filaments partially exposed by cutting away or omitting the outer braid.

Fig. 3 shows a sectional view along the line 3-3 in Fig. 2.

As is shown in the drawing, the exemplary realization of the suture material of the invention shows a tubular braid 1, which is composed of very thin synthetic fibers braided together. A number of very thin platinum fibers or pure gold fibers 3 are inserted into the tubular braid 1 over its entire length. A surgical needle 4 is joined integrally with both ends or with one end of the tubular braid 1 which surrounds the platinum fibers or the pure gold fibers that are inserted into the braid 1.

As for fibers 2 that form the tubular braid 1, those fibers can be used that have a smooth surface and a high durability, resistance to abrasion, bending strength and tensile strength, for example, polyfluoroethylene fibers or polyester fibers.

The tubular braid 1 is formed by braiding together a number of fibers 2 with a lengthwise mass of $1/9 \times 10^2$ tex, with 16 fibers being used in the exemplary realization shown in Figs 2 and 3.

The very thin platinum fibers or the very thin pure gold fibers 3 that are inserted into the tubular braid 1 have a diameter of about 50 μ m, with about 20 fibers of this kind being used. These platinum fibers or these pure gold fibers have no effect on the internal organs when they are in the body.

The surgical needle 4 is composed of stainless steel or a special steel.

By means of the above described suture material, the realization of suturing can take place smoothly without injuring the internal organs unnecessarily, since the fibers 2 of which the braid 1 is composed have smooth surfaces. Furthermore, because of the type of material of which it is composed, the suture material does not transport any blood or other body fluid by capillary action. Adhesion and transmission of bacteria can therefore be hindered without any special treatment of the suture material and even when bacteria are transferred the infected region can be healed easily.

Further, after the surgery, it is possible to make radiological observations of tissue formation in the living body and of the result of long-term tissue formation after the post-operative treatment, for example the formation of an anastomosis, and it is likewise possible to observe on x-ray film progressive changes in the state of the area operated on with its migration and other heretofore unknown functions of the body organs, which is extremely useful for the medical treatment.

The surgical suture material of the invention is thus best suited for the surgical implantation of artificial organs.

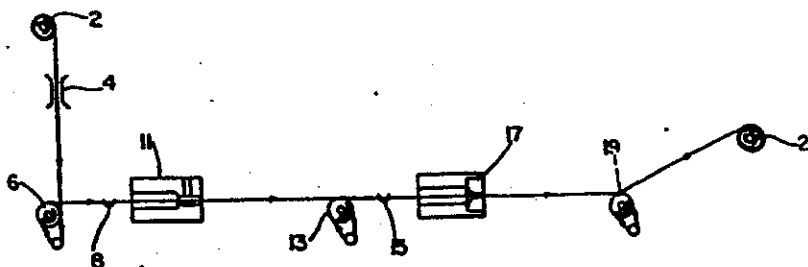
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(34) Title: COMPOSITE SURGICAL SUTURES



(57) Abstract

A composite surgical suture of extraordinary high knot strength and capable of use over a range of United States Pharmacopoeia (USP) suture sizes is prepared by coating or covering a core of a fiber-forming synthetic polymer material having a knot tenacity of at least 7 grams per denier with a conventional suture material. Illustrative of suitable core materials are Kevlar and high strength fully chain-extended crystalline polyethylene.

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COMPOSITE SURGICAL SUTURES

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to improved surgical sutures having extremely high knot strength and to methods for their preparation. More particularly, the invention is directed to composite surgical sutures having a knot strength that enables them to be used over a range of suture sizes classified by the United States Pharmacopeia (USP).

Brief Description of the Prior Art

Surgical sutures are generally divided into two broad classes: (1) absorbable sutures, either natural or synthetic, which are absorbed by the body and (2) non-absorbable sutures, which remain in the body for prolonged periods of time or are removed when the wound heals.

From the patient's viewpoint, whether an absorbable or non-absorbable suture is employed, assuming no toxicity of the suture implant, it is a surgical dictum that the finest suture should be used and that the knot should have the least mass. This dictum is based upon the belief that problems in suture implants are directly related to the size of the suture and the bulk of the mass, i.e., the larger the bulk, the greater the probability of trouble in healing.

Undoubtedly, this was the rationale for the original establishment of the USP classification which divides non-absorbable sutures into seventeen sizes: 10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6, 7. A few additional

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sizes are used which are not USP. Considering that silk was the most widely used non-absorbable suture in the mid-twenties and thirties, this size differentiation was based upon manufacturing. These seventeen sizes could be differentiated one from another by eye. If a finer differentiation were desired, it would not be accomplished because of the variation in the raw material as extruded by the silk worm. This classification has been quite useful. Obviously, the number of sizes cannot be considered "standardization" by any means. The sizes are numerous. Unfortunately, it has not been possible to coalesce size because the finer sizes do not have the adequate knot break strength to substitute for the next size.

A further long term problem in surgery is post-operative hernia. It is a truism that scar tissue never achieves the tensile strength of normal tissue. Hernias have occurred many years post-operably through the scar. If a suture were developed which would leave as a residue a non-absorbable suture to support that scar tissue, it would undoubtedly decrease and most likely eliminate the post-operative hernia as a complication.

Composite sutures having a reinforcing core are known in the prior art. None, however, achieve the aforementioned characteristics desired in a suture.

Accordingly, it is an object of the invention to provide a surgical suture with knot strengths so great that suture of much less foreign material is left in the body.

Another object of the invention is to provide a surgical suture having a knot strength that renders it useful over a range of surgical sizes within the USP classification of graded suture sizes, and thus

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having the ability to replace the USP graded scale of sizes with just a few finer sutures whose strength would cover the entire range.

A further object of the invention is to provide a composite suture which leaves a residue of non-absorbable suture to support scar tissue and, therefore, decreases or eliminates post-operative hernia as a complication.

Another object of the invention is to provide a method of preparing surgical sutures having extremely high knot strength whose surface characteristics can be tailored to meet desired properties.

A further object of the invention is to provide composite sutures capable of using needles which more closely approximate the outer diameter of the suture.

A further object of the invention is to provide a composite suture having lateral strength, that is, a suture stabilized against abrasion, kinking and/or fibrillation during knotting.

SUMMARY OF THE INVENTION

These and other objects of the invention are obtained by a sterile, surgical suture having an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier coated with a film and fiber-forming surgical material, said coated core, when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

The elongated core of the sutures of the invention can be formed of any fiber-forming synthetic polymer, such as a polyamide, polyolefin, polyester

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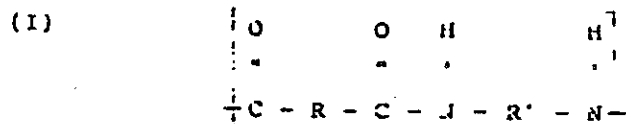
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and the like, having a straight pull tenacity of at least 15 grams/denier, preferably up to 70 or more grams/denier and a knot tenacity of at least 7 grams/denier, preferably up to 30 or more grams/denier. By "knot tenacity" as used herein and in the appended claims is meant knot break strength divided by the denier. Unless the synthetic polymer making up the suture core of the invention meets the aforementioned knot tenacity properties, the resulting coated core fails to provide a suture which achieves the desired objects of the invention.

Illustrative of synthetic polymer materials suitable for use as the core of the suture of the invention are fiber-forming aromatic polyamides in which the chain extending bonds from each aromatic nucleus are essentially coaxial or parallel and oppositely directed. The term "aromatic nucleus" is used herein to include individual enchainned aromatic rings and fused-ring aromatic divalent radicals. The preferred polymers include carbocyclic aromatic polyamides containing up to 2 aromatic rings, including enchainned non-fused rings (e.g. 4, 4'-biphenylene) or fused rings (e.g. 1, 5-naphthalene) per amide linkage. The chain-extending bonds from these aromatic rings are para-oriented and/or essentially coaxial or parallel and oppositely directed.

Highly preferred polyamides are characterized by recurring units of the formula:



wherein R and R' (when the chain extending bonds are essentially coaxial) are selected from the group of:

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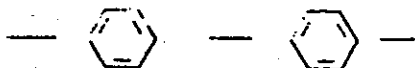
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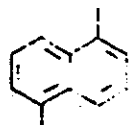


1,4-phenylene, and



4,4'-biphenylene

and R and R' (when the chain extending bonds are essentially parallel) are selected from the group of:



1,5-naphthylene, and

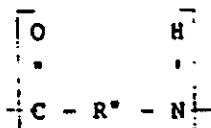


2,6-naphthylene

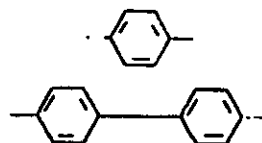
R and R' may be the same or different and may contain substituents on the aromatic nuclei.

Additional highly preferred polyamides of this invention are characterized by recurring units of the formula:

(II)



wherein R'' is selected from the group of:



Similarly R' may contain substituents on the aromatic nuclei.

As previously stated, the aromatic nuclei of the polymers of this invention may bear substituents. These substituents should be non-reactive during the polymerization and preferably also should be non-reactive (e.g. thermally) during subsequent processing of the polymer, e.g., heat treating of a shaped fiber thereof. Such reactivity is undesirable in that it may cause cross-

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linking of the polymer and may adversely effect the dope and/or fiber properties. Among the preferred non-reactive substituents may be names halogens (e.g., methoxy and ethoxy), cyano, acetyl, and nitro. Other suitable substituents non-reactive during the polymerization will be evident to those skilled in the art and are contemplated herein provided such do not adversely affect the desired properties of the dopes and/or fibers of this invention, e.g., due to factors such as steric hindrance. Generally, it is preferred that no more than two (and more preferably no more than one) suitable substituents be present per aromatic nucleus. However, more than two such substituents may suitably be present if the substituent is a relatively small group e.g., methyl.

Both homo- and co-polyamides having substituted or unsubstituted aromatic nuclei, as described above, are well suited for the dopes and fibers of this invention. Random copolymers are preferred copolymers. By the term "random" is meant that the copolymer consists of molecules containing large numbers of units comprised of two or more different types in irregular sequence. The units may be of AB (e.g., from p-aminobenzoyl chloride hydrochloride), AA (e.g., from p-phenylenediamine or 2,6-dichloro-p-phenylene diamine), or BB (e.g., from terephthaloyl or 4,4'-biphenzoyl chloride) type or mixtures of these, provided always that the requirements of stoichiometry for high polymer formation are met. It is not necessary that the relative numbers of the different types of the unit be the same in different molecules or even in different portions of a single molecule.

One or more of these polymers may suitably be

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used in the fibers of this invention, i.e., a single homopolymer; a single copolymer; or homopolymer and/or copolymer blends are suitable herein.

While the polymer chains described above consist essentially of amide links (- CONH -) and aromatic ring nuclei as described above, the polymers useful for preparing the core of this invention may also comprise up to about 10 percent (mole basis) of units not conforming to the above-cited description, e.g., aromatic polyamide-forming units whose chain extending bonds are other than coaxial or parallel and oppositely directed, e.g., they may be metaoriented, or of linkages other than amide, e.g., urea or ester groups.

Among the suitable aromatic polyamides may be named poly(p-benzamide); poly(p-phenylene terephthalamide); poly(2-chloro-p-phenylene terephthalamide); poly(2,6-dichloro-p-phenylene 2,6-naphthalamide); poly(p-phenylene p,p'-biphenyldicarboxamide); poly(p,p'-phenylene benzamide); poly(1,5-naphthylene terephthalamide); ordered aromatic copolyamides such as e.g., copoly(p,p'-diaminobenzanilide terephthalamide), and random copolyamides such as, e.g., copoly(p-benzamide/m-benzamide) (95/5); and many others.

These aromatic polyamides generally have an inherent viscosity and preferably greater than 1.0. Inherent viscosity (η_{inh}) defined by the following equation:

$$\eta_{inh} = [\ln(\eta_{rel})/C]$$

wherein (η_{rel}) represents the relative viscosity and C represents a concentration of 0.5 gram of the polymer in 100 ml of solvent. Exemplary of such aromatic polyamides are those known as the "Kevlar"

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series, products of the DuPont corporation, which generally have a straight pull tenacity of about 18 to 25 grams per denier and a knot tenacity of at least about 7 grams per denier. Further examples of such aromatic polyamides and their methods of preparation can be found, for instance, in U.S. Patent Nos. 3,063,966, 3,600,350, 3,671,542 and 3,919,587 all incorporated herein by reference.

Another example of a synthetic polymer suitable for use as the core of the suture of the invention are high strength polyolefins such as polyethylene which provides fibers having a straight pull tenacity of about 25-50 grams/denier and a knot tenacity of about 7 to 17 grams/denier. These polyolefin fibers are characterized by full chain extension and high crystallization and can be prepared: (1) by ultradrawing of the solidified crystalline polyolefin material that is, by further development of the traditional cold drawing process, and (2) by extending the chains in random state (melt or solution) and inducing them to crystallize in the extended form subsequently. Polyolefins having these characteristics and their method of preparation are described in Keller, A. and Barham, P.J. "High Modulus Fibres", Plastics and Rubber International, February, Volume 6, No. 1 (1981), herein incorporated by reference.

The core of the surgical suture of the invention can be either a monofilament or of multifilament construction. The latter is ordinarily preferred since the coating of suture material subsequently applied generally exhibits stronger adhesion to multifilament cores. The liquified suture material coating tends to penetrate and fill the interstices of a multifilament core as well as

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coating the core, thereby anchoring the coating thereto. Multifilament cores can take the form of braids, twisted polyfilaments, yarns and the like.* It should be noted that while the synthetic polymer materials contemplated for use as the core of the composite sutures of the invention, have high axial strength, they are not ordinarily suitable for use as sutures since they do not possess the necessary lateral strength and, therefore, tend to abrade, kink and/or fibrillate during knotting. Coating of the core with a suture material pursuant to the present invention has been found to unexpectedly stabilize, i.e. provide lateral strength resistance against such action thereby rendering suitable for use as sutures these synthetic polymer fibers normally unsuitable for such use.

The surgical suture material used to coat the core can be any film-forming material commonly used in the construction of absorbable and non-absorbable sutures. In general these suture materials when drawn into fibers exhibit straight tensile strengths of about 4 to 10 grams/denier. Examples of the non-absorbable type suture materials are silk (fibroin), polyolefins, such as polyethylene and polypropylene, polyesters such as polyethylene terephthalate and nylon. Examples of absorbable type materials useful as the coating for *

The suture material in the form of multi or monofilament yarn may also be present initially as a core around which the high strength yarn which eventually becomes the core in the finished suture is braided or twisted or it may be formed into a plied, twisted, braided or co-mingled construction with the high strength yarn.



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the core include collagen and the synthetic absorbable materials such as polylactide, polyglycolide and copolymers of lactide and glycolide with each other and with other reactive monomers such as those described, for instance, in U.S. Patent Nos. 3,636,952 and 2,683,136, which patents are herewith incorporated by reference. Such synthetic absorbable polymers are sometimes referred to herein as simply homopolymers and copolymers of lactide and glycolide.

The amount of suture material coated onto the core will vary depending upon the construction of the core, whether monofilament or multifilament, the number and tightness of braid or twist, the particular tensile strength and knot tenacity of the core, the particular suture material used as the coating and its nature, e.g. melt, solution or solid. In general, when the coating is a non-absorbable suture material, the coating will constitute about 5 to about 10% by weight of the coated core. On the other hand, when the coating is an absorbable suture material, the coating may constitute about 5 to 90% by weight of the coated core.

The coatings can be applied by a variety of suitable techniques well known in the coating art. For example, the coatings can be applied to the core by solution coating, melt coating, extrusion coating and the like.

In melt coating, for example, the uncoated core under tension is slowly passed through a melt of the suture material and then through a die having an orifice smaller than the upper diameter specification for the suture size desired, heated above the melting point of the coating materials, to trim

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off excess coating material and shape the composite. Multiple coatings may be applied if necessary.

In solution coating, the suture material is dissolved in a suitable solvent and the core is slowly passed through the coating solution thus formed. The treated core is then passed continuously through a tubular oven heated to an elevated temperature to evaporate the solvent and coalesce and solidify the suture material that remains.

A preferred coating technique when the core being coated is of multifilament construction comprises initially either solution coating or melt coating the multifilament core while the latter is held under a suitable tension and allowing the liquified coating material to penetrate or infiltrate the interstices of the core, thereby forming roots which help anchor the coating of the core. A second layer of the same suture material may then be applied to the impregnated core by any of the conventional coating methods.

In a typical extrusion coating process the core is passed through the cross-head die of a conventional wire coating extrusion apparatus. Pellets of the coating material are introduced into the plastification zone of the extruder wherein they are plasticized into a melt which is forced through the annular die of the extruder and onto the core.

Which coating technique is employed will usually depend upon the particular core utilized. Aromatic polyamide cores, for example, lend themselves to melt or extrusion coating because of their high melting points. The high strength polyethylene cores, on the other hand, have

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relatively low melting points, e.g. about 145°C, and must be treated differently. With them, solution coating of the monoor multi-filament cores is the chief method.

According to a preferred embodiment of the invention, when the core being coated is an aromatic polyamide, it is subjected to both a precoating stage and finish coating stage, each of which will be discussed below in more detail.

Impregnation/Precoating Stage

The impregnation/precoating operation of the invention can be conducted using a thread composed of a core made up of multifilaments of a suture material and a plurality of fibers of a synthetic polymer having a tenacity of at least 18 grams/-denier and knot tenacity of at least 7 grams/-denier. The thread can be formed in the usual manner as by twisting, braiding, etc., a plurality of the synthetic polymer fibers around the suture material core. The thread, that is, the covered core is then heated to temperatures above the melting point of the multifilament core material passing it through any suitable oven during which passage the suture material melts and under the tension developed and/or applied exudes upward through the polyfilamentous synthetic polymer component and onto its surface. The amount of coating employed should be sufficient to not only fill all the interstices of the multifilament core component during the melting period but to also coat the surface of the yarn or thread component. Any excess coating material which may have melted out is trimmed off. While the heating of the covered core mixed yarns can be effected with or

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Without stretching of the thread in some instances, a better final suture is obtained when the yarn is maintained under tension with little or no stretch applied at this stage. It is at this stage that the basic solid coated core structure is developed.

The impregnated and coated core is then passed through a heated dye which trims coating nubs from the core and otherwise smooths the external surface of the thread. Stretch may also be applied during the smoothing operation, but again, best results are obtained with no or minimum stretch. The thread may be passed through the heating oven or smoothing die as many times as is necessary to obtain a smooth, nub-free surface. Advantageously, in smoothing down the nubs not only should excess surface coating be removed, but some of it should be used to fill the ups and down of the thread's surface in order to obtain a sufficiently smooth undercoat structure. If this is not done, the coating remaining on the surface follows the contours of the thread and any subsequently applied coating will follow these contours.

The temperatures employed in the heating oven will vary depending on the coating employed, the proportions of coating material to core, the speed at which the core is passed through the oven and whether the heating and/or smoothing is conducted under stretch conditions. As aforementioned, the temperature should be raised above the melting point to a level at which the coating material exudes through the thread as a gelatinous mass which can then be seen on the surface of the thread when it cools. Excessively high temperatures which thin the coating material to a point where it runs off should be avoided as they tend to exude too

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much coating material and fail to produce a solid case structure.

Generally speaking, when the impregnation/precoating operation is conducted under stretch conditions, distribution of the coating material throughout the thread and exudation to the surface occurs at lower temperatures than when no stretch is applied. It is important to note, however, that giving the core a high level of stretch in the impregnation/precoating operation reduces or eliminates the ability to apply stretch in the subsequent finish coating stage, in accordance with the preferred embodiment of the invention described below, where it may be used to adjust finished suture properties such as break elongation by additional heat treatment of the highly stretched precoated thread.

The optimum melting temperatures employed in the impregnation/precoating operation will depend primarily upon which suture coating material is employed. The smoothing die temperature will also be above the melting point of the coating material and below the melting point of the core. Usually it will conform closely to the temperature employed in the impregnation/precoating stage preferably about 5 to 15 degrees below that used in the impregnation/precoating stage.

Finish Coating Stage

In the preferred embodiment of the invention, the final stage in obtaining the composite suture structure is to melt extrude coating material onto the smoothed impregnated/precoated thread. Any of the conventional extrusion apparatuses can be employed for this purpose. The smooth precoated

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thread is simply fed through the extrusion coating die and coated with additional coating material of the same type as used in the impregnation/precoating stage. As aforementioned, it is important to note that the smooth impregnated/precoated thread subjected to the coating stage be essentially free of an undulating surface. The extrusion temperatures employed in the impregnation/precoating stage although it has been found that the higher the extrusion coating temperature, other conditions being equal, the greater the finished suture diameter. This is due to decreased melt viscosity with increased temperature which results in increased polymer flow under a given applied force.

The following examples are included to further illustrate the novel composite sutures of the invention and their preparation. In the examples, reference is made to the following drawings wherein: Fig. 1 is a schematic drawing of an apparatus useful in the impregnation/precoating stage of the present invention; Fig. 2 is a schematic drawing of an apparatus useful in the extrusion coating of the suture impregnated and precoated by use of the apparatus of Fig. 1; and Fig. 3 is a cross-section of the extrusion die in Fig. 2 on a larger scale.

Example 1

Directing attention to the drawings, using a conventional New England Butt braider machine 4 strands of "Kevlar", a tradenamed material of DuPont de Nemours, of 30-50 denier having a straight pull tenacity of approximately 7.5 grams per denier are braided around a single core of continuous 40 denier polypropylene having a straight pull tenac-

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ity of approximately 4 grams/denier. The raw braid thus formed is wound around a reel 2, and fed through a tensioner 4, about a feed roll (Godet) 6, guide 8 and into a heated 10 cm long tubular oven. The lumen of an extrusion coating die without feed serve this purpose and is designated Heated Zone I in Fig. 1. A draw roll (Godet) 13 pulls the raw braid through the oven without stretch, that is, at a stretch ratio (SR) of 1:1. The Heated Zone I is maintained at a temperature of 230°C. Under these conditions all the polypropylene melts and is entirely distributed throughout the braid interstices and onto the surface of the braid. No solid polypropylene core residue remains.

As the braid emerges from Heated Zone I, large quantities of excess polypropylene which have melted out are trimmed off manually. The braid then continues through a Guide 15 to Heated Zone II which contains a smoothing die 17 having a 0.2 mm diameter that trims and smooths down nubs that are formed on the braid. Heated Zone II is maintained at a temperature of about 220°C for the smoothing operation. The smoothed braid is pulled through Heated Zone II by a draw roll (Godet) 19 and onto receiving reel 21. The speed at which the braid passes through both Heated Zone I and II is approximately 1-1.8 M/min. The precoated braid is passed through the smoothing die 17 three times so as to obtain an impregnated/precoated braid of the desired smoothness.

Referring to Fig. 2, reel 31 of smooth impregnated/precoated braid prepared as above is passed through a tensioner 33, to feed roll (Godet) 35 which feeds the braid through guide 37 into extrusion coating die apparatus indicated generally



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as 39. Polypropylene chips are melted in heated reservoir 41 maintained at a temperature of 260°C and the melt is forced by means of extruding weights 43 applied at a force of 0.233 kg to a piston 45 into and through the extrusion coating die.

Directing particular attention to Fig. 3, the extruding coating apparatus is comprised of a holder indicated generally as 47 which houses a hollow lumen member 49 a spinneret 57 having an outlet 52. The lumen member 49 essentially positioned within the holder 47 so as to provide an annular chamber 53. A gasket 55 seals one end of the member 49 within the holder while the other end is supported by slotted plate 60. The lumen member contains an inlet 59 and an outlet 61. Between outlet 61 and outlet 52 of the spinneret 57 is positioned a hollow needle 63. The impregnated/precoated thread 65 passes consecutively through lumen member 49, hollow needle 63, outlet 52 and is coated with melt as it emerged from the die. The coating die is maintained at a coating temperature of 235°C.

The coated filament is then taken up on draw roll 48 which applies stretch. Tension is let down on draw roll 50 which is run more slowly than draw roll 48. The yarn velocity is 1.43 M/min. and the total stretch ratio (SR) is 1.02. The finished suture is finally wound around receiving reel 51.

The result is a finished composite suture with a 5/0 diameter "Kevlar" core accounting for approximately 90% of the cross-sectional area and exhibiting a knot break strength of about 3.2 pounds. A knot break strength of 3.2 pounds is equivalent to USP limits of size 2.0 monofilament suture. Thus,



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the composite suture prepared can be used as a 5/0, 4/0, or 3/0 suture.

Example II

The process of Example I is repeated substituting a polyethylene terephthalate core for polypropylene core and extrusion coating in extrusion coating die apparatus 39 with polyethylene terephthalate. The result is a composite suture having a 5/0 diameter "Kevlar" core accounting for approximately 90% of the cross-sectional volume coated with polyethylene terephthalate exhibiting a knot break strength of about 3.5 pounds which is a knot break strength above the USP limits for a 2/0 size suture. Therefore, the composite suture prepared could be used for sizes 5/0, 4/0, 3/0 and 2/0 according to the physician's wishes.

Example III

Fibroin (silk) is dissolved in a aqueous solution of 62% zinc chloride to give a solution having fibroin weight % concentrations in the range of 5-20%. The resulting solution is maintained at approximately its boiling point and "Kevlar" yarn of Example I is pulled through the solution at a constant rate as to fully impregnate and coat the yarn. The impregnated and coated yarn is then dried by passing it through a tubular oven maintained at heating temperatures up to 130°C. The heat treatment evaporates the solvent and helps to form a continuous fibroin film. The composite suture is then washed with cold water to remove residual zinc chloride.

The resulting composite suture with a size 5/0 "Kevlar" core containing approximately 5% by weight fibroin exhibits a knot break strength of approximately 3.5 pounds which is equivalent to a silk



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suture of size 2/0. In other words, the silk-coated "Kevlar" composite suture could be used instead of silk in the following sizes: 5/0, 4/0, 3/0 and 2/0.

Example IV

A size 5/0 high strength fully chain-extended polyethylene multifilament yarn having a straight pull tenacity of 50 grams/denier and a knot tenacity of 15 grams/denier is pulled through a 10% solution of polyethylene terephthalate in a solvent mixture of methylene chloride containing 31% by weight hexafluoroisopropanol and then passed through a die to trim off excess solution. The coated core is dried in air and the process repeated to build up the coating to a final composite suture containing 10% by weight polyethylene terephthalate. The composite is washed with water and dried again. The resulting composite suture could be used for sizes 5/0, 4/0, 3/0, 2/0 and 1/0.

Example V

Example I is repeated substituting a polyglycolic acid (PGA) core for the polypropylene core and PGA resin for the polypropylene chips. The resulting "Kevlar"/polyglycolic acid composite has a minimum knot break strength in the range of 1550-1700 grams. Since commercial non-absorbable "Prolene" sutures of size 3/0 has a knot strength of 1550-1650 grams, this means that a size 3/0 "Kevlar"/polyglycolic acid suture will retain the knot break strength of 3/0 "Prolene" after absorption of all the polyglycolic acid. Thus, the "Kevlar"/polyglycolic acid suture prepared could be used for sized 3/0, 4/0 and 5/0.

When 5/0 size "Kevlar" reinforcing core is used with a non-reinforcing PGA coating, the core by

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itself will give a knot strength midway between size 4/0 and 5/0 based on "Prolene" knot strength but above the USP standards for 4/0. Thus, PGA coated "Kevlar" composites with a 6/0 core could be used for size 6/0, 5/0 and possible size 4/0.

With size 7/0 reinforcing core and PGA non-supportive coating 6/0 strength is obtained. Thus, PGA coated, 7/0 core "Kevlar" can be used for sizes 6/0 and 7/0.

Using high strength, extended chain polyethylene having 50 gram/denier straight breaking tenacity, with approximately 1/3 of this converting to knot tenacity, a 5/0 size reinforcing high strength polyethylene core of about 0.140 mm in diameter will impart at least the knot strength of a 2/0 suture to the composite. Thus, a PGA-coated high strength polyethylene 5/0 core can be used to make sizes 2/0, 3/0, 4/0 and 5/0 absorbable, non-absorbable composite sutures.

With high strength polyethylene 6/0 size reinforcing core of about 0.90 mm diameter and a non-supporting PGA coating, the core itself will provide enough knot strength for sizes 4/0, 5/0 and 6/0 based on the knot strength of "Prolene".

With high strength polyethylene 7/0 size reinforcing core of about .060 - .065 mm in diameter and non-reinforcing PGA coating, the core itself will give knot strength sufficient for 5/0, 6/0 and 7/0 composites based on the knot strengths of "Prolene".

With higher strength materials or by increasing the knot strength of the materials mentioned here, a wider spectrum of sizes could be covered with the same fine sized reinforcing core.

In commercial production, needles may be

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attached to one end of the composite sutures of the invention and the sutures may be packed in sterile containers. Inasmuch as the sutures are stable for long periods of time without a conditioning fluid, the sutures may be dry packed in glass tubes or plastic envelopes. Conditioning fluid may be used to assure maintenance of sterility or as a rust preventing medium for the needle. Eyeless needles are preferred since they cause less tissue damage. Conveniently, the composite sutures of the present invention are formed at convenient lengths, attached to eyeless needle, wound on reels if desired, and placed in containers such as plastic envelopes. The sutures may then be sterilized with ethylene oxide or other conventional gaseous sterilizing agents in accordance with known practices. Alternatively, the sutures may be sealed in the envelopes and then sterilized by using heat and radiation including x-rays, gamma rays, electrons, neutrons, etc.

Another advantage offered by the composite sutures of the invention is that needles of smaller diameter can be attached thereto. In accordance with this feature of the invention the outside cover or coating of suture material at the end of the composite suture is removed by any suitable means as, for instance, by dissolving the cover using a solvent which solubilizes the cover but not the core. The core at the end of the suture is thereby exposed and onto the core is attached as, for instance, by swagging a needle of smaller outer diameter than would be used with a suture of the same outer diameter. The following example illustrates this feature of applicants' invention:

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Example VI

The end of a composite suture prepared according to the general procedure of Example I and having an outer diameter of approximately 0.012 inch is dipped one-eighth inch into boiling xylene until the polypropylene cover softens. The polypropylene cover is then manually scrapped off to expose the 5/0 "Kevlar" core. A 0.014 inch diameter needle is swagged onto the core to provide a suture with a needle having a cross-sectional area reduced approximately two-thirds that of needles required for sutures having a 0.012 inch diameter.

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IT IS CLAIMED:

1. A sterile, surgical suture comprising an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams per denier coated with a filament fiber-forming surgical suture material, said coated core, when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

2. A sterile, surgical suture according to claim 1 wherein the synthetic polymer is an aromatic polyamide.

3. A sterile, surgical suture according to claim 1 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

4. A sterile, surgical suture according to claim 1 wherein the aromatic polyamide is poly(1,4-benzamide).

5. A sterile, surgical suture according to claim 1 wherein the synthetic polymer is a fully chain-extended polyethylene having a straight pull tenacity of about 30 to 50 grams/denier.

6. A sterile, surgical suture according to claim 1 wherein the surgical suture material is fibroin.

7. A sterile, surgical suture according to claim 1 wherein the surgical suture material is polyester.

8. A sterile, surgical suture according to claim 1 wherein the polyester is polyethylene terephthalate.

9. A sterile, surgical suture according to claim 1 wherein the surgical suture material is polyolefin having a straight pull tenacity of about

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21. A sterile, surgical suture according to claim 2 wherein the core is a plurality of fibers of said synthetic polymer in a twisted yarn or braided construction.

22. A sterile, surgical suture according to claim 20 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

23. A sterile, surgical suture according to claim 1 wherein the coating of film-forming suture material comprises 5 to 10% by weight of the suture.

24. A sterile, surgical suture according to claim 13 wherein the coating of film-forming suture material comprises 5 to 90% by weight of the suture.

25. A method of producing a surgical suture having a knot strength rendering it useful over a range of USP suture grade sizes comprising coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier, with a fiber and film-forming surgical suture material, said coated core when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

26. A method according to claim 25 wherein said coating is effected by solution coating.

27. A method according to claim 25 wherein said coating is effected by melting coating.

28. A method according to claim 25 wherein the coating comprises heating under tension a thread comprised of a plurality of synthetic polymer fibers having a knot tenacity of at least 7 grams/denier in the form of a cover and at least one fiber of a meltable surgical suture material in the form of a core, at an elevated temperature sufficient to melt and liquify the fiber or fibers

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4 to 10 grams/denier.

10. A sterile, surgical suture according to claim 1 wherein the polyolefin is polyethylene.

11. A sterile, surgical suture according to claim 1 wherein the polyolefin is polypropylene.

12. A sterile, surgical suture according to claim 1 wherein the surgical suture material is collagen.

13. A sterile, surgical suture according to claim 1 wherein the surgical suture material is a film-forming absorbable synthetic polymer.

14. A sterile, surgical suture according to claim 13 wherein the absorbable synthetic polymer is selected from the group consisting of film-forming homopolymers and copolymers of lactide and glycolide.

15. A sterile, surgical suture according to claim 14 wherein the absorbable synthetic polymer is a homopolymer of glycolide.

16. A sterile, surgical suture according to claim 14 wherein the absorbable synthetic polymer is a homopolymer of lactide.

17. A sterile, surgical suture according to claim 1 wherein the core is in monofilament construction.

18. A sterile, surgical suture according to claim 2 wherein the core is in monofilament construction.

19. A sterile, surgical suture according to claim 18 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

20. A sterile, surgical suture according to claim 1 wherein the core is a plurality of fibers of said synthetic polymer in a twisted yarn or braided construction.

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of surgical suture material but not the fibers of said cover, permitting the liquified surgical suture material to distribute itself throughout the interstices of the cover and onto the surface thereof so as to form a coating on said cover, which is thereby converted to the core of the finished composite suture, then smoothing said coating.

29. A method according to claim 28 wherein said smoothing is effected by passing said heated thread through a heated smoothing die.

30. A method according to claim 29 wherein the surgical suture material is selected from polyolefin and polyester.

31. A method according to claim 25 wherein the coating comprises heating under tension a thread comprised of a plurality of synthetic polymer fibers having a straight pull tensile strength of at least 18 grams/denier and a knot tenacity of at least 7 grams/denier in the form of a cover and at least one fiber of a meltable surgical suture material in the form of a core, at an elevated temperature sufficient to melt and liquify the fiber or fibers of surgical suture material but not the fibers of said cover, permitting the liquified surgical suture material to distribute itself throughout the interstices of the cover and onto the surface thereof so as to form a coating on said cover, which is thereby converted to the core of the finished composite suture, smoothing said coating and melt extruding similar surgical suture material onto said smoothed coating.

32. A method according to claim 31 wherein the surgical suture material is selected from polyolefin and polyester.

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-27-

33. A method according to claim 25 wherein the coating is effected by solution coating.

34. A method of producing a surgical suture having a knot strength rendering it useful over a range of USP suture grade sizes comprising coating an elongated core of synthetic polymer having a knot tenacity of at least 7 grams/denier and a lateral strength insufficient to prevent abrasion, fibrillation or kinking on knotting with a film and fiber-forming surgical material in an amount sufficient to increase the lateral strength of said core and provide resistance against said abrasion, fibrillation or kinking on knotting, said coated core, when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

35. A sterile, surgical suture according to claim 1 having a needle attached to said core.

36. A sterile, surgical suture according to claim 35 wherein the synthetic polymer is an aromatic polyamide.

37. A sterile, surgical suture according to claim 35 wherein the aromatic polyamide is poly(p-Phenylene terephthalamide).

38. A sterile, surgical suture according to claim 35 wherein the aromatic polyamide is poly(1,4-benzamide).

39. A sterile, surgical suture according to claim 35 wherein the synthetic polymer is a fully chain-extended polyethylene having a straight pull tenacity of about 30 to 50 grams/denier.

DePuy Mitek, Inc. v. Arthrex, Inc.
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PCT/LS84/00918

1/1

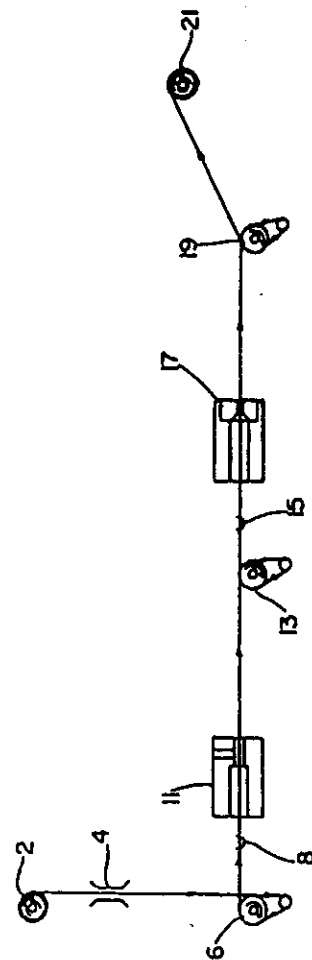


FIG. 1

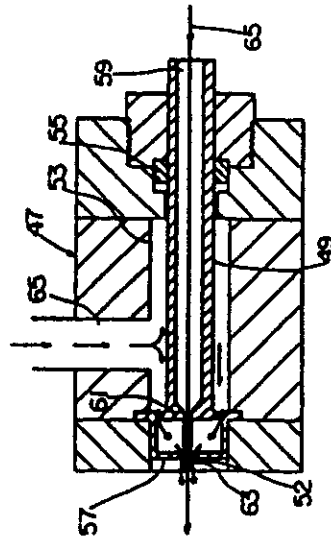


FIG. 3

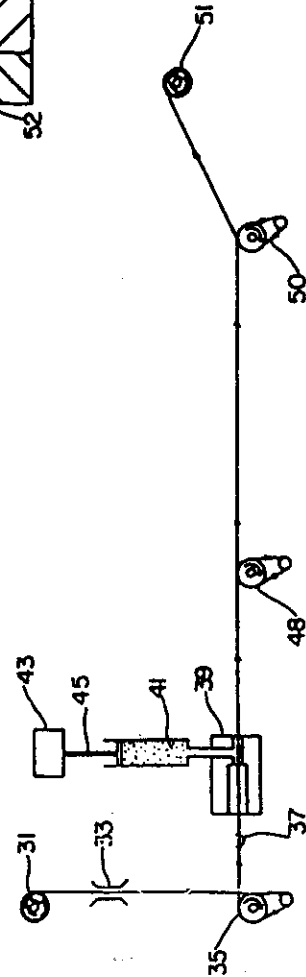


FIG. 2

INTERNATIONAL SEARCH REPORT

International Application No PCT/US84/00918

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) *			
According to International Patent Classification (IPC) or to both: National Classification and IPC			
Int Cl ⁸ A61L 17/00			
US CL 128/335.5			
II. FIELDS SEARCHED			
Minimum Documentation Searched *			
Classification System	Classification Symbols		
US	128/329R, 334R-335.5, Dig. 8, Dig. 18 28/140, 165, 166, 169 66/169R-170, 202 8/Dig. 21 8/490, 529-533, 115.5-115.7, 130.1-132, Dig. 3.		
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched *			
cont'd Dig. 9			
III. DOCUMENTS CONSIDERED TO BE RELEVANT **			
Category *	Citation of Document, ** with indication, where appropriate, of the relevant passages **	Relevant to Claim No. **	
X, Y	US, A, 3,791,388	12 February 1974 HUNTER	1, 6-9, 11-17, 20, 23-35
Y	US, A, 4,014,973	29 March 1977 THOMPSON	23, 24, 31
Y	US, A, 3,359,983	26 December 1967 NORTHEY	5, 10, 23, 24, 39
Y	US, A, 3,630,205	28 December 1971 LISTNER	5, 10, 23, 24, 39
X, Y	US, A, 4,204,542	27 May 1980 BOKROS	23, 24, 35-38
X, Y	US, A, 4,336,357	22 June 1982 BARTOLI	23, 24, 35-38
<p>* Special categories of cited documents: **</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document relating to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"A" document member of the same patent family</p>			
IV. CERTIFICATION			
Date of the Actual Completion of the International Search *		Date of Mailing of the International Search Report *	
31 JULY 1984		17 AUG 1984	
International Searching Authority *		Signature of Authorized Officer *	
ISA/US		C. FRED ROSENBAUM	

Form PCT/ISA/70 (second sheet) (October 1983)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000180

International Application No. PCT/US84/00918

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSERCHABLE ¹⁰

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers . because they relate to subject matter ¹¹ not required to be searched by this Authority, namely:

2. ☐ Claim numbers . because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out ¹², specifically:

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING ¹¹

This International Searching Authority found multiple inventions in this international application as follows:

Claims 1-24 and 35-39 are drawn to a surgical suture.

Claims 25-34 are drawn to a method of making a surgical suture.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
4. ☒ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

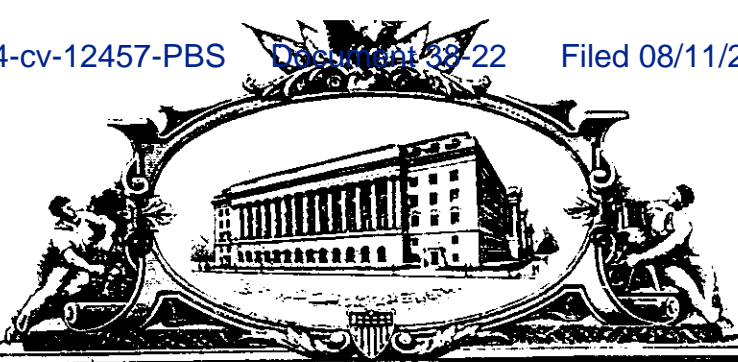
Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA:216 (supplemental sheet (2)) (October 1981)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI000181

[illegible]



THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

February 04, 2005

THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE
RECORDS OF THIS OFFICE OF THE FILE WRAPPER AND CONTENTS
OF:

APPLICATION NUMBER: 07/838,511

FILING DATE: February 19, 1992

PATENT NUMBER: 5,314,446

ISSUE DATE: May 24, 1994



By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

N. Woodson
N. WOODSON

Certifying Officer

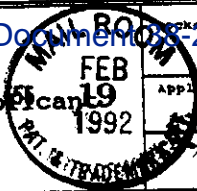
PART *2* OF *2* PART(S)

DePuy Mitek, Inc. v. Arthrex, Inc.

C.A. No.04-12457 PBS

DMI000184

List of Prior Art Cited by Applicant



2-19-92

group 1504

U.S. PATENT DOCUMENTS

Exam'r Init.		Document No.	Date	Name	Class	Sub Class	File Date
CUR	AA	3,942,532	3/9/76	Hunter et al.	128	335.5	8/15/74
CUR	AB	4,624,256	11/25/86	Messier et al.	128	335.5	8/11/85
CUR	AC	3,527,650	9/8/70	Block, A.	117	7	12/21/67
CUR	AD	4,470,941	9/11/84	Kurtz, L.	264	136	6/2/82
CUR	AE	3,187,752	6/8/65	Glick, A.	128	335.5	4/27/62
CUR	AF	4,043,344	8/23/77	Landi et al.	128	335.5	9/20/76
CUR	AG	4,047,533	8/13/77	Perciaccante et al.	128	335.5	9/20/76
CUR	AH	4,946,467	8/7/90	Ohi et al.	606	228	3/8/89
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

Exam'r Init.		Document No.	Date	Country	Class	Sub Class	Translate Yes	No
CUR	AL	GB 2 218 312A	11/15/89	United Kingdom	A01K	91/00	✓	—
CUR	AM	DE 2949920	3/19/81	Germany	A61F	1/00	✓	—
CUR	AN	WO 86/00020	1/3/86	PCT	A61L	17/00	✓	—
	AO							
	AP							

OTHER REFERENCES (include author, title, date, pertinent pages, etc.)

	AR		
	AS		
	AT		

Examiner CHRIS RAIMUND	Date Considered JUNE 25, 1992
*Examiner: See note on original PTO form concerning initialing and MPEP 609 compliance. Include copy of this form with next communication to applicant.	

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark OfficeAddress: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/828,511	02/19/92	HUNTER	ETH-782

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08903-7003

EXAMINER

SAIMUND

ART UNIT

PAPER NUMBER

1504

DATE MAILED: 07/08/92

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS
☒ This application has been examined
 ☐ Responsive to communication filed on _____
 ☐ This action is made final.

 A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
 Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

- 1.
- ☒
- Claims
- 1 - 24
- are pending in the application.

Of the above, claims 1 - 20 are withdrawn from consideration.

- 2.
- ☐
- Claims _____ have been cancelled.

- 3.
- ☐
- Claims _____ are allowed.

- 4.
- ☒
- Claims
- 21 - 24
- are rejected.

- 5.
- ☐
- Claims _____ are objected to.

- 6.
- ☒
- Claims
- 1 - 24
- are subject to restriction or election requirement.

- 7.
- ☐
- This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

- 8.
- ☐
- Formal drawings are required in response to this Office action.

- 9.
- ☐
- The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are
- ☐
- acceptable.
- ☐
- not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

- 10.
- ☐
- The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been
- ☐
- approved by the examiner.
- ☐
- disapproved by the examiner (see explanation).

- 11.
- ☐
- The proposed drawing correction, filed on _____, has been
- ☐
- approved.
- ☐
- disapproved (see explanation).

- 12.
- ☐
- Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has
- ☐
- been received
- ☐
- not been received
-
- ☐
- been filed in parent application, serial no. _____; filed on _____

- 13.
- ☐
- Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

- 14.
- ☐
- Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

DePuy Mitek, Inc. v. Arthrex, Inc.

C.A. No.04-12457 PBS

DMI000186

Serial No. 838,511

-2-

Art Unit 1504

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-20, drawn to a heterogeneous braid, classified in Class 57, subclass 243.

II. Claims 21-24, drawn to a surgical suture, classified in Class 600, subclass 231.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as mutually exclusive species in intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (M.P.E.P. § 806.04(b), 3rd paragraph), and the species are patentably distinct (M.P.E.P. § 806.04(h)).

In the instant case, the intermediate product is deemed to be useful as a fishing line and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

Serial No. 838,511

-3-

Art Unit 1504

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Matthew S. Goodwin on June 23, 1992 a provisional election was made without traverse to prosecute the invention of Group II, claims 21-24. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1-20 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Serial No. 838,511

-4-

Art Unit 1504

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 21-24 are rejected under 35 U.S.C. § 103 as being unpatentable over Burgess (U.K. Patent Application No. 2,218,312A).

Burgess discloses a fishing line of braided construction comprising filaments of polyethylene and filaments of polyester or nylon. Such a braid is disclosed to have the low stretchability of polyethylene and the low coefficient of friction of polyester. (See page 1). It is therefore known to braid filaments of two dissimilar polymers together to form a structure which embodies the desirable properties of each fiber.

Braided sutures are well known in the art. Many of the requirements of sutures are comparable to those of fishing line—strength, low stretchability, flexibility, low coefficient of friction etc. Indeed, many of the same materials are used for both of these applications. It would therefore have been

Serial No. 838,511

-5-


Art Unit 1504

obvious, in view of Burgess, to use a heterogeneous braid for a suture. Claims 21 and 23 are therefore unpatentable over Burgess.

Synthetic, fiber forming polymers are widely employed as filaments in braided sutures. In German Patent Application DE 2949920A1, for example, surgical sutures made from braided polytetrafluoroethylene (PTFE) fibers or polyester fibers are disclosed. As polyester fibers are noted for their strength and PTFE fibers for their low coefficient of friction, it would have been obvious to use a braid comprising both types of filaments as a suture.

It is also known in the art to a braid around longitudinally extending core filaments. Ohi et al, for example, disclose a core comprising a plurality of synthetic fiber filaments (column 1, lines 57-60). Polyester filament are specifically disclosed (column 2, lines 4-9). It would therefore have been obvious to dispose a heterogeneous braid comprising polyester and polytetrafluoroethylene fibers around a core of polyester fibers to form a suture. Claims 22 and 24 are therefore unpatentable over Burgess.

Any inquiry concerning this communication should be directed to Chris Raimund at telephone number (703) 308-3452.


Chris Raimund:jp
July 06, 1992



DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000190

GEORGE F. LESMES
SUPERVISORY PATENT EXAMINER
GROUP 150

PTO FORM 948
(Rev 5-91)U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office

ATTACHMENT TO PAPER NUMBER

3

APPLICATION NUMBER

838511

GROUP

1504

NOTICE OF DRAFTSMAN'S PATENT DRAWING REVIEW

The PTO Draftsmen review all originally filed drawings regardless of whether they were designated as informal or formal.

The drawings filed 2/19/92A. ☒ are approved.

B. ☐ are objected to under 37 CFR 1.84 for reason(s) checked below. The examiner will require submission of new, corrected drawings at the appropriate time. Corrected drawings must be submitted according to the instructions listed on the back of this Notice.

1. Paper and ink. 37 CFR 1.84(a)

- ☐ Poor Quality Paper. Must Be White.
Transparent Paper Not Allowed.
Sheet(s) _____

2. Size of Sheet and Margins. 37 CFR 1.84(b)
Acceptable Paper Sizes and Margins

Paper Size			
Margin	8 1/2 by 14 inches	8 1/2 by 13 inches	DIN size A4 21 by 29.7 cm.
Top	2 inches	1 inch	2.5 cm.
Left	1/4 inch	1/4 inch	2.5 cm.
Right	1/4 inch	1/4 inch	1.5 cm.
Bottom	1/4 inch	1/4 inch	1.0 cm.

- ☐ Proper Size Paper Required. All Sheets Must be Same Size.
Sheet(s) _____

- ☐ Proper Margins Required.
Sheet(s) _____

- ☐ Top ☐ Right
☐ Left ☐ Bottom

3. Character of Lines. 37 CFR 1.84(c)

- ☐ Lines Pale, Rough and Blurred, or Jagged. Fig(s) _____

- ☐ Solid Black Shading Not Allowed.
Fig(s) _____

4. ☐ Photographs Not Approved.

- ☐ Comments:

5. Hatching and Shading. 37 CFR 1.84(d)

- ☐ Shade Lines are Required.
Fig(s) _____

- ☐ Criss-Cross Hatching Not Allowed.
Fig(s) _____

- ☐ Double Line Hatching Not Allowed.
Fig(s) _____

- ☐ Parts in Section Must be Hatched Properly. Fig(s) _____

6. Reference Characters. 37 CFR 1.84(f)

- ☐ Reference Characters Poor or Rough and Blurred. Fig(s) _____

- ☐ Minimum 1/8 inch (3.2 mm.) in height is required. Fig(s) _____

- ☐ Figure Legends Poor or Placed Incorrectly. Fig(s) _____

7. Views. 37 CFR 1.84(i) & (j)

- ☐ Figures Must be Numbered Separately.

- ☐ Figures Must Not be Connected
Fig(s) _____

8. Identification of Drawings. 37 CFR 1.84(l)

- ☐ Extraneous Matter or Copy Machine Marks Not Allowed. Fig(s) _____

9. ☐ Changes Not Completed from Prior PTO-948 dated _____

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS

DMI000191

Telephone inquiries concerning this review should be directed to the Chief Draftsman at telephone number (703) 557-6404.

7c
Reviewing Draftsman

3/6/92
Date

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities—37 CFR 1.85

File new drawings with the changes incorporated therein. The art unit number, serial number and number of drawing sheets should be written on the drawings in accordance with 37 CFR 1.84(l). Applicant may delay filing of the new drawings until receipt of the "Notice of Allowability" (PTOL-37). If delayed, the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for response in the "Notice of Allowability" (PTOL-37). Extensions of time may be obtained under the provisions of 37 CFR 1.136. The drawing should be filed as a separate paper with a transmittal letter addressed to the Official Draftsman.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the three month shortened statutory period set in the "Notice of Allowability" (PTOL-37). Within that three month period, two weeks should be allowed for review by the Office of the correction. If a correction is determined to be unacceptable by the Office, applicant must arrange to have acceptable correction re-submitted within the original three month period to avoid the necessity of obtaining an extension of time and paying the extension fee. Therefore, applicant should file corrected drawings as soon as possible.

Failure to take corrective action within set (or extended) period will result in **ABANDONMENT** of the Application.

2. Corrections other than informalities Noted by the Draftsman on the PTO-948

All changes to the drawings, other than informalities noted by the Draftsman, **MUST** be made in the same manner as above except that, normally, a red ink sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.



ETH 782
Batch No. 567

B
H3P
S12M

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter et al.

Serial No.: 838,511

Art Unit: 1504

Filed : February 19, 1992

Examiner: C. Raimund

For : **STERILIZED HETEROGENOUS BRAIDS**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

February 14, 1994
(Date of Deposit)

Hal Brent Woodrow
Name of applicant, assignee, or Registered Representative
Hal Brent Woodrow
(Signature)

February 14, 1994
(Date of Signature)

9200
ordered
5/18/94

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT UNDER 37 CFR §312

Dear Sir:

This is responsive to the Examiner's Amendment attached to the Notice of Allowance dated November 15, 1993, at which time a shortened statutory period for response of three months was set.

In the Claims

Please amend the claims as follows:

In Claim 10 after "claim" and before "wherein" please delete "8" and insert therefor -- 21 -- .

OK to enter -
MSE

Hal Brent Woodrow
Hal Brent Woodrow
Reg. No. 32,501
Attorney for Applicant(s)



ETH-78

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair Hunter et al.

Serial No.: 838,511

Art Unit: 1504

Filed : February 19, 1992

Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 6, 1992
(Date of Deposit)

Matthew S. Goodrin
Name of applicant, assignee, or Registered Representative

Matthew S. Goodrin
(Signature)

August 6, 1992
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

RECEIVED
AUG 17 1992
GROUP 150

AMENDMENT

Dear Sir:

Responsive to the Office Action of July 8, 1992, please reconsider the above-identified application in view of the following remarks.

REMARKS

1. Restriction to the invention of either Group I, claims 1-20, or Group II, claims 21-24, was required. Applicants reaffirm without traverse to prosecute the invention of Group II, claims 21-24. This election is made without prejudice to Applicants' right to file a divisional application directed to the non-elected invention of Group I, claims 1-20.

2. Claims 21-24 were rejected under 35 USC §103 as being unpatentable over Burgess. The Examiner has asserted that it would have been obvious in view of Burgess to use a heterogeneous braid for a suture. Applicants respectfully traverse this rejection.

DePuy Mitek, Inc. v. Arthrex, Inc.

C.A. No.04-12457 PBS

DMI000194

The Examiner mistakenly believes that the requirements for a braided suture are comparable to those of a fishing line. However, nothing could be further from the truth.

One of the most important requirements for a braided suture is that it have outstanding knot strength when a knot is secured on the suture braid. Indeed, this requirement may be the most important requirement for a braided suture. This is so because the suture knot is what keeps a stitched wound intact. If the knot fails, then the wound can reopen and consequently the braided suture has failed as well.

Applicants recognized the importance of knot strength when attempting to overcome the shortcomings of the braided sutures disclosed in the art. In preferred embodiments of the invention, Applicants' claimed suture exhibits improved handling properties without sacrificing physical strength or knot security (see the specification at page 5, lines 4-7). In addition, numerous braided sutures were tested to determine their knot strength and knot security (see the examples at the end of the specification). The determination of knot security is described in the specification at page 12, lines 26-33.

In contrast, knot strength is not even mentioned in Burgess. Although it may be argued that it may be necessary to secure a knot on a fishing line to hold the hook to the line, the security and strength of the knot are not nearly as critical for this application. In fact, the fishing line of Burgess would have poor knot strength properties because of its braided construction, as set forth in more detail below.

Some of the braid filaments of the Burgess fishing line are composed of high tensile polythene thread. This thread gives the line minimal stretchability (see Burgess at page 1, lines 12-13). Although this thread has great strength properties, it suffers from

is a good idea for a fishing line because high strength and low elongation, or low stretchability, are important criteria. Low elongation is an important requirement for a fishing line because it makes it possible for the fisherman to apply force on the hook when, for example, the fish is caught. If the line were stretchable, then the force exerted by the fisherman would be taken up by the stretching action of the line. This would clearly be an undesirable property for a fishing line to exhibit. Therefore, the property requirements for fishing line yield a braid with poor knot strength and security, and the requirements for sutures yield a braid which has by necessity excellent knot strength and security.

In addition to the contrasting requirements for braided sutures and fishing line resulting from the critical need to tie strong and secure knots on braided sutures, other requirements concerning the knot make the braid for a fishing line unsuitable for use as sutures. For example, a surgeon must be able to make a conventional square knot at a very fast pace for patient safety. Clearly, a knot on a fishing line for a hook can be made at a much slower pace, and with a much more complex knot. Also, it is necessary during suturing to form a pre-knot on the braided suture, and the pre-knot must be subsequently slid down the suture until it is adjacent the body tissue desired to be stitched. Once the knot is placed at the desired location, additional throws on the knot can be added for knot security. This requires a braided suture which is stretchable and resilient so that this operation can be performed. Obviously, there is no such similar requirement for a fishing line.

In view of the dissimilarities in property requirements between sutures and fishing line, there would simply be no incentive for a medical designer who wishes to improve the properties of braided sutures to study the art related to braided fishing lines. Even if he did use the teachings of the fishing line art to modify a

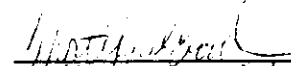
suture, then he would inevitably design an unacceptable suture. Accordingly, Applicants respectfully submit that the rejection is in error and therefore it should be withdrawn.

It is noted that the Examiner has discussed German Patent Application DE 2949920 A 1 and Ohi et al. as evidence of the state of the art concerning the types of filaments used in braided sutures, and core/sheath braid construction. Applicants do not wish to rely on these specific limitations set forth in claims 22 and 24 for patentability, but instead rely on the inventive features set forth in the broader independent claim, claim 21.

Accordingly, for the reasons set forth above, Applicants respectfully request the Examiner to withdraw the rejection of claims 21-24 under 35 USC 103 as being unpatentable over Burgess.

3. Since all formal requirements appear to have been met, except for the submission of formal drawings, and claims 21-24 are patentable over the art of record, Applicants respectfully solicit a Notice of Allowability.

Respectfully submitted,


Matthew S. Goodwin
Attorney for Applicant
Reg. No. 32,839

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
August 6, 1992

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No. 838,511

Case Docket No.: ETH-782

Application of Alastair Hunter et al.

Filed February 19, 1992

For STERILIZED HETEROGENEOUS BRAIDS

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is an amendment in the above-identified application.

[] No additional fee is enclosed because this application was filed prior to October 25, 1965 (effective date of Public Law 89-83).

[X] No additional fee is required.

[X] One stamped, self-addressed postcard for the PTO Mail Room date stamp.

[] Petition For Extension of Time and charge to Deposit Account of Appropriate Fee.

The fee has been calculated as shown below.

CLAIMS AS AMENDED

(1)	(2)	(3)	(4)	(5)	(6)	(7)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL CLAIMS	* XX	minus	** XX	= 0	x \$20	= \$ XXX.XX
INDEP. CLAIMS	* XX	minus	*** XX	= XX	x \$72	= \$ XXX.XX
				TOTAL ADDITIONAL FEE FOR THIS AMENDMENT		\$ XXX.XX

- * If the entry in Col.2 is less than the entry in Col.4, write "0" in Col.5
 ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
 *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

[] Charge \$ ###.## to Deposit Account No. 10-750/DOCKET NO/ATTY. Three copies of this sheet are enclosed.

[X] Please charge any additional fees in connection with the filing of this communication, or credit overpayment, to Deposit Account No. 10-750/ETH-782/MSG. Three copies of this sheet are enclosed.

[] A check in the amount of \$ _____ is attached.

Matthew S. Goodwin
 Attorney of Record
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 August 6, 1992

DePuy Mitek, Inc. v. Arthrex, Inc.
 C.A. No.04-12457 PBS
DMI000198

Application of Alastair Hunter et al.

Serial No. 838,511

Filed February 19, 1992

For STERILIZED HETEROGENEOUS BRAIDS

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

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CLAIMS AS AMENDED

(1)	(2)	(3)	(4)	(5)	(6)	(7)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL CLAIMS	* XX	minus	** XX	= 0	x \$20	= \$ XXX.XX
INDEP. CLAIMS	* XX	minus	*** XX	= XX	x \$72	= \$ XXX.XX
			TOTAL ADDITIONAL FEE FOR THIS AMENDMENT			\$ XXX.XX

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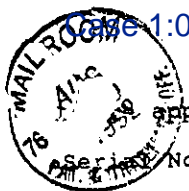
[X] Please charge any additional fees in connection with the filing of this communication, or credit overpayment, to Deposit Account No. 10-750/ETH-782/MSG. Three copies of this sheet are enclosed.

[] A check in the amount of \$ _____ is attached.

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Attorney of Record
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August 6, 1992

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000199



Application of Alastair Hunter et al.
Serial No. 838,511
Filed February 19, 1992

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For STERILIZED HETEROGENEOUS BRAIDS
THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

RECEIVED

AUG 17 1992

Sir: GROUP 150

Transmitted herewith is an amendment in the above-identified application.

[] No additional fee is enclosed because this application was filed prior to October 25, 1965 (effective date of Public Law 89-83).

[X] No additional fee is required.

[X] One stamped, self-addressed postcard for the PTO Mail Room date stamp.

[] Petition For Extension of Time and charge to Deposit Account of Appropriate Fee.

The fee has been calculated as shown below.

CLAIMS AS AMENDED						
(1)	(2)	(3)	(4)	(5)	(6)	(7)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL CLAIMS	* XX	minus	** XX	= 0	x \$20	= \$ XXX.XX
INDEP. CLAIMS	* XX	minus	*** XX	= XX	x \$72	= \$ XXX.XX
				TOTAL ADDITIONAL FEE FOR THIS AMENDMENT		\$ XXX.XX

- * If the entry in Col.2 is less than the entry in Col.4, write "0" in Col.5
- ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
- *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

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(908) 524-2791
August 6, 1992

SERIAL NUMBER	FILING DATE	HUNTER FIRST NAMED INVENTOR	A	EXAMINER DOCKET NO.
077333-311	08/11/92			

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

RAIMUND, C
EXAMINER

1481 UNIT PAPER NUMBER

11/02/92

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on August 6, 1992 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1 - 24 are pending in the application.
Of the above, claims 1 - 20 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 21 - 24 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

DePuy Mitek, Inc. v. Arthrex, Inc.

C.A. No. 04-12457 PBS

DMI000201

Serial No. 838,511

-2-

Art Unit 1504

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21 and 23 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Doddi et al.

Doddie et al disclose a surgical suture comprising filaments of two different polymers in a braided configuration (column 9, lines 47-56). The suture is specifically disclosed attached to a needle (column 11, lines 53-54). Claims 21 and 23 are therefore unpatentable over Doddie et al.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Serial No. 838,511

-3-

Art Unit 1504

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 22 and 24 are rejected under 35 U.S.C. § 103 as being unpatentable over Kaplan et al taken with Doddi et al.

Kaplan et al discloses a ligament prosthesis comprising a core component and a braided sheath component (see Figure 3). The core component is "made up of one or more biocompatible, essentially non-bioabsorbable..." filaments (column 9, lines 1-3). The sheath yarn component may be fabricated "from individual filaments having more than two different chemical compositions, one or more of which optionally being nonbioabsorbable" (column 9, lines 25-28).

Doddie et al disclose suitable biocompatible, non-absorbable fibers to include PET and PTFE (column 9, lines 51-53). It would have been obvious to form the device of Kaplan with a sheath component of PTFE and PET and a core component of PET. PTFE is known to impart improved knot run down properties to sutures (see Block U.S. Patent No. 3,527,650). PET is noted for its low cost

Serial No. 838,511

-4-

Art Unit 1504

and high strength. Claims 22 and 24 are therefore unpatentable over Kaplan et al taken with Doddi et al.

Applicant's arguments with respect to claims 21-24 have been considered but are deemed to be moot in view of the new grounds of rejection.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication should be directed to Chris Raimund at telephone number (703) 308-3452.



Chris Raimund:jp
October 29, 1992



GEORGE F. LESMES
SUPERVISORY PATENT EXAMINER
GROUP 150

FORM PTO-892 (REV. 2-92)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		SERIAL NO. 838,511	GROUP/ART UNIT 1504	ATTACHMENT TO PAPER NUMBER		
NOTICE OF REFERENCES CITED				APPLICANT(S) Hunter et al.				
U.S. PATENT DOCUMENTS								
	DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE		
A	4052988	10/1977	Dodd et al.	128	335.5	—		
B	5147400	09/1992	Kaplan et al.	623	13	09/1990		
C	5116360	05/1992	Pinchuk et al.	623	1	12/1990		
D								
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FOREIGN PATENT DOCUMENTS								
	DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS. DWG.	PP. SPEC.
L								
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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)								
R								
S								
T								
U								
EXAMINER CHRIS RAIMUND				DATE OCT. 26, 1992				
<p>* A copy of this reference is not being furnished with this office action. (See Manual of Patent Examining Procedure, section 707.05 (a).)</p>								

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI000205

United States Patent [19]

[11] 4,052,988

Doddi et al.

[45] Oct. 11, 1977

[54] SYNTHETIC ABSORBABLE SURGICAL
DEVICES OF POLY-DIOXANONE

[75] Inventors: Namassivaya Doddi; Charles C.
Versfelt, both of Somerville; David
Wasserman, Springfield, all of N.J.

[73] Assignee: Ethicon, Inc., Somerville, N.J.

[21] Appl. No.: 648,236

[22] Filed: Jan. 12, 1976

[51] Int. Cl.² A61L 17/00

[52] U.S. Cl. 128/335.5; 3/1;
128/92 B; 128/92 D; 260/78.3 R

[58] Field of Search 128/335.5, 92;
260/78.3; 3/1

[56] References Cited

U.S. PATENT DOCUMENTS

3,063,967	11/1962	Schultz	260/78.3
3,063,968	11/1962	Schultz	260/78.3
3,190,858	6/1965	Cox et al.	260/78.3
3,297,033	1/1967	Schmitt et al.	128/335.5

3,636,956	1/1972	Schneider et al.	128/335.5
3,645,941	2/1972	Snapp et al.	260/78.3
3,867,190	2/1975	Schmitt et al.	128/335.5 X
3,960,152	6/1976	Auguri et al.	128/335.5

OTHER PUBLICATIONS

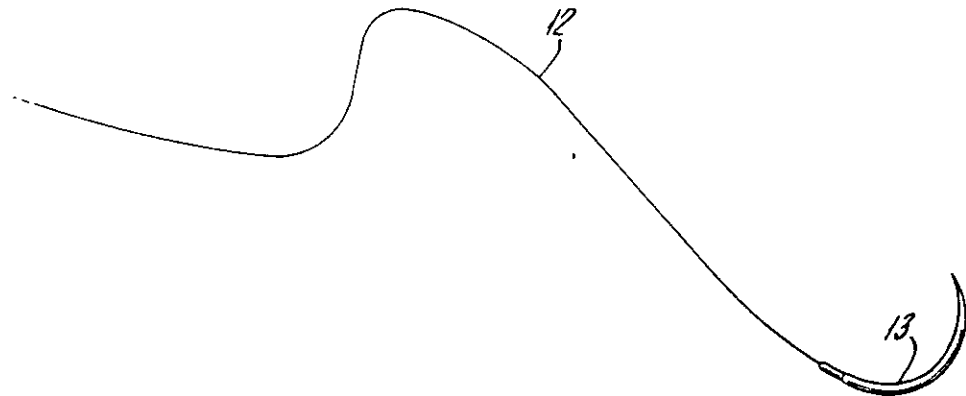
Palomaa et al.—Ber. Deut. Chem. Gesellsch., vol. 66B,
pp. 1629–1632 (1933).

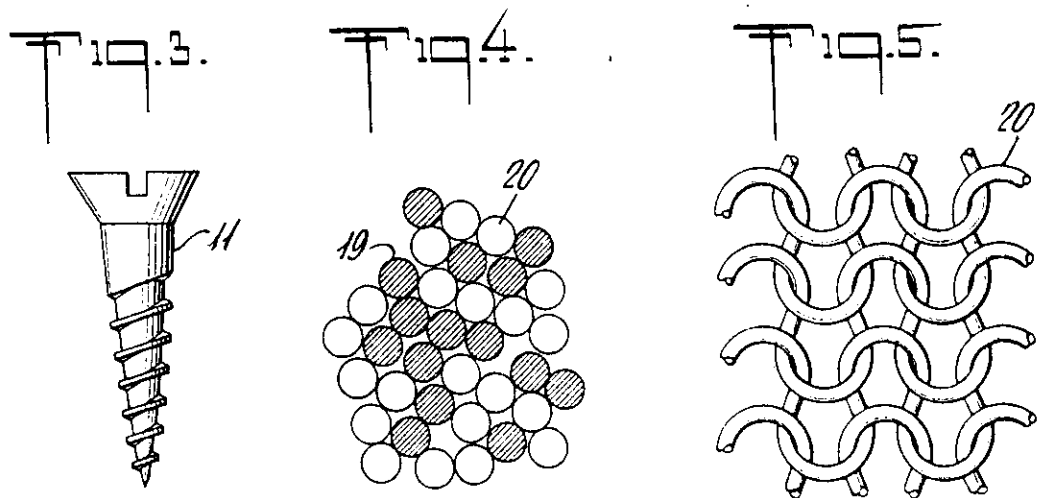
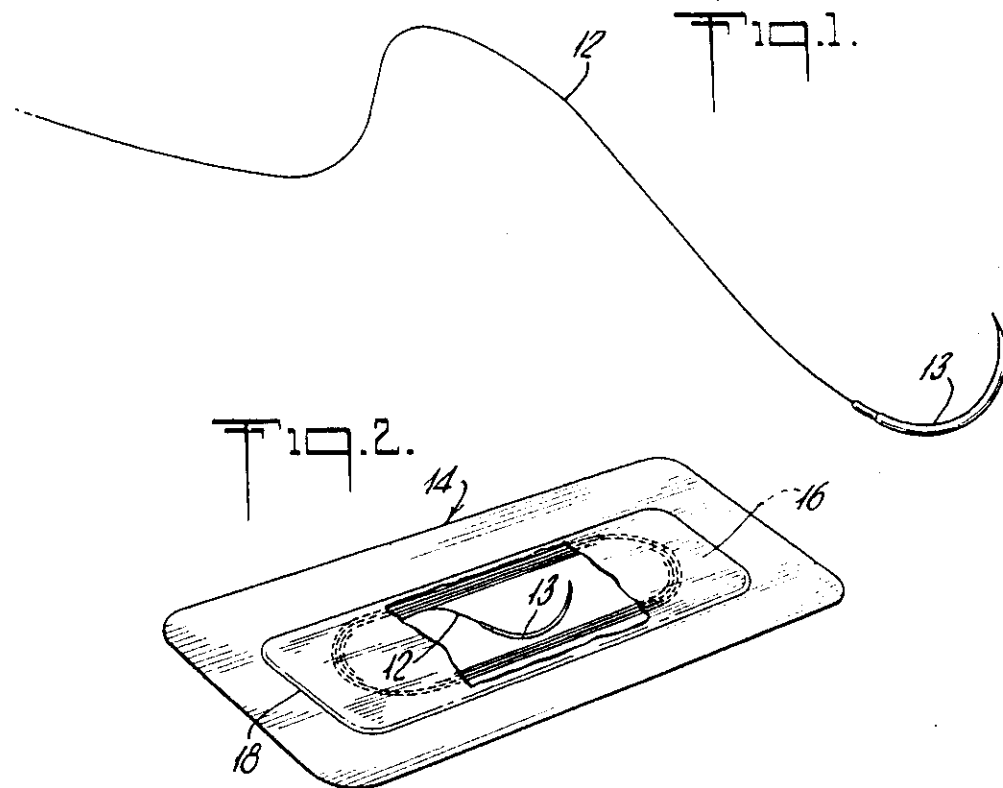
Primary Examiner—Dalton L. Truluck
Attorney, Agent, or Firm—Wayne R. Eberhardt

[57] ABSTRACT

Synthetic absorbable sutures and other surgical devices are prepared from polymers of p-dioxanone and 1,4-dioxepan-2-one, and alkyl substituted derivatives thereof. Monofilament sutures of oriented fibers are characterized by good tensile and knot strength and a high level of flexibility and softness. The sutures have good in vivo strength retention and are slowly absorbed without significant tissue reaction.

39 Claims, 5 Drawing Figures





4,052,988

1

SYNTHETIC ABSORBABLE SURGICAL DEVICES OF POLY-DIOXANONE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to synthetic absorbable sutures, and more particularly, to synthetic absorbable sutures comprising extruded and oriented filaments of polymers of p-dioxanone or 1,4-dioxepan-2-one.

2. Description of Prior Art

Absorbable suture materials have traditionally been natural collagenous materials obtained from sheep or beef intestine, commonly known as catgut. More recently, it has been proposed to manufacture synthetic absorbable sutures from polyesters of hydroxycarboxylic acids, notably polylactide, polyglycolide, and copolymers of lactide and glycolide. Such synthetic absorbable sutures are described in U.S. Pat. Nos. 3,636,956, 3,297,033 and elsewhere in the literature.

Among the requirements of an ideal absorbable suture are that it should have good handling properties, should approximate and hold tissue for proper healing with minimal tearing and tissue damage, should have adequate straight tensile and knot strength, should be controllably uniform in properties including dimensional stability within the body, should be sterilizable, should be absorbable by living tissue, preferably at a constant rate regardless of the place in the body or the condition of the patient, without causing such unfavorable tissue reactions as walling off, granuloma formation, excessive edema, etc., and finally should be capable of being properly and easily tied into surgical knots.

While multifilament sutures manufactured from polymers of lactide and glycolide fulfill the above requirements to a large degree, monofilament sutures of these materials are considerably less flexible than catgut and these synthetic sutures are accordingly generally limited to a multifilament, braided construction. Sutures of glycolide polymers are also not suitable for sterilization by radiation without suffering severe degradation of physical properties.

The present invention provides synthetic absorbable sutures having a high degree of softness and flexibility which allows the sutures to be used in monofilament form. The sutures can also be sterilized with cobalt 60 radiation without serious loss of suture strength. It is accordingly an object of the present invention to provide synthetic absorbable sutures having unique and desirable properties not available with the sutures of the prior art.

We have discovered that polymers of p-dioxanone and 1,4-dioxepan-2-one prepared from monomers of very high purity can be melt extruded into pliable, monofilament fibers which are slowly absorbed in animal tissue without significant adverse tissue reaction. The fibers have good tensile and knot strength and good in vivo strength retention, and can be sterilized with cobalt 60 without serious loss of these properties.

Polymers of p-dioxanone and fibers extruded therefrom have been known in the art. U.S. Pat. Nos. 3,063,967 and '968 for example, describe the polymerization of p-dioxanone and the preparation of films and fibers therefrom. The low tensile strength of fibers prepared in accordance with the teachings of these references, however, make these fibers generally unsuitable for use as surgical sutures. Moreover, there was no appreciation in these references of the absorbability of such

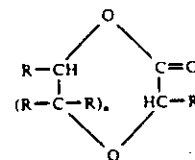
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fibers which were reported to be resistant to the effects of saline and distilled water.

Other references dealing with the polymerization of p-dioxanone include, but are not limited to, U.S. Pat. Nos. 3,190,858, 3,391,126 and 3,645,941 which disclose various catalysts for the polymerization of lactones such as p-dioxanone, and U.S. Pat. No. 3,020,289 which describes the polymerization of p-dioxanone in the presence of sulfuric acid. None of these references suggest polymers of p-dioxanone or 1,4-dioxepan-2-one for use in the preparation of synthetic absorbable sutures in accordance with the present invention.

SUMMARY

Synthetic absorbable sutures are prepared from polymers of monomers having the formula:



wherein R' and each R are hydrogen, methyl or ethyl and n is 1 or 2, provided that when n is 2, at least two R groups are hydrogen.

Polymers prepared by the polymerization of very pure monomers are melt extruded into filaments suitable for use as synthetic absorbable sutures. The filaments are characterized by high tensile and knot strength, good strength retention in vivo, and a Young's modulus of less than about 600,000 psi corresponding to a high degree of softness and flexibility.

DESCRIPTION OF DRAWINGS

FIG. 1 is a perspective view of a needle-suture combination;

FIG. 2 is a perspective view of a suture-needle combination within a hermetically sealed container;

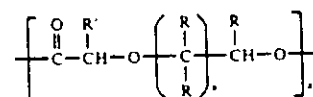
FIG. 3 illustrates a screw machined from the polymer of the present invention;

FIG. 4 is a cross-sectional view of a composite yarn containing filaments of different composition and;

FIG. 5 is a plan view of a surgical fabric knitted from fibers of the present invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

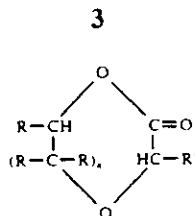
Polymers of the present invention are comprised of units having the general formula:



wherein R' and R are individually hydrogen, methyl, or ethyl, n is 1 or 2 provided that when n is 2 at least two R groups are hydrogen, and x is the degree of polymerization resulting in a fiber forming polymer.

The polymer is conveniently prepared from highly purified monomer, i.e., monomer of at least about 98 percent purity, having the formula:

4,052,988



wherein R, R' and n are as defined above. When n is 1, the monomer is preferably p-dioxanone, methyl-p-dioxanone, or dimethyl-p-dioxanone. When n is 2, the monomer is preferably 1,4-dioxepan-2-one.

A particularly preferred monomer is p-dioxanone, and the following description and examples which are presented by way of illustration are directed primarily to the preparation and polymerization of that monomer, it being understood that certain variations may apply to other monomers and polymers encompassed by the above formula as will be readily apparent to those skilled in the art. Para-dioxanone monomer is conveniently prepared by reacting ethylene glycol, metallic sodium, and chloroacetic acid as hereinafter described in detail. The resulting monomer is preferably purified to 99+ % purity by multiple distillations and recrystallizations. We have discovered that high monomer purity is necessary to obtain a high molecular weight polymer and ultimately, a fiber of good tensile and dry knot strength.

The purified monomer is polymerized at a temperature of 20° to 130° C, most preferably above 75° C, in the presence of an organometallic catalyst as hereinafter described in detail to obtain a high molecular weight polymer of p-dioxanone characterized by an inherent viscosity of at least about 0.50 measured as a 0.1% solution in tetrachloroethane at 25° C, and a crystallinity of at least about 20% as determined by X-ray diffraction.

The polymer is melt extruded through a spinneret in a conventional manner to form one or more filaments which are subsequently drawn about 4x to 6x in order to achieve molecular orientation and improve tensile properties. The resulting oriented filaments have good tensile and dry knot strength and good in vivo strength retention.

To further improve dimensional stability and tensile strength retention, the oriented filaments may be subjected to an annealing treatment. This optional annealing treatment consists of heating the filaments to a temperature of from about 50° to 105° C, most preferably from about 50° to 80° C while restraining the filaments to prevent any substantial shrinkage. The filaments are held at the annealing temperature for a few seconds to several days or longer depending on the temperature and processing conditions. In general, annealing at 50° to 80° C for up to about 24 hours is satisfactory for p-dioxanone. Optimum annealing time and temperature for maximum improvement in fiber in vivo strength retention and dimensional stability is readily determined for each fiber composition.

Since the function of a suture is to join and hold severed tissue until healing is well along, and to prevent separation as a result of movement or exercise, a suture must meet certain minimum standards of strength. It is particularly important that strength be maintained when knots are tied and during the actual procedure of drawing tight a suitable knot. Oriented filaments of the present invention are characterized by a straight tensile strength of at least about 40,000 psi and a knot strength of at least about 30,000 psi, although significantly higher

strengths are possible as will be apparent from the following examples.

The preparation of high molecular weight oriented filaments of poly-p-dioxanone and other polymers of the present invention is further illustrated by the following examples where all percentages are by weight unless otherwise noted.

EXAMPLE 1

A. Preparation of p-dioxanone

Metallic sodium is dissolved in a large excess of ethylene glycol to obtain a glycolate which is further reacted with about 0.5 mols of chloroacetic acid per mole of sodium to yield the sodium salt of the hydroxy acid. Excess ethylene glycol and by-products of the reaction are removed by distillation and by washing with acetone. The sodium salt is converted to the free hydroxy acid by the addition of hydrochloric acid, and the resulting sodium chloride is removed by precipitation with ethanol followed by filtration.

The hydroxy acid filtrate is slowly heated up to about 200° C, preferably in the presence of $MgCO_3$, to remove alcohol and water by distillation. Upon further heating at atmospheric pressure the p-dioxanone is formed and distills over at a head temperature of between about 200°-220° C. The purity of the crude dioxanone product is generally about 60-70 percent as determined by gas chromatography and yields are in the order of 50 to 70 percent.

The crude p-dioxanone is further purified to about 98 percent by redistillation, and finally purified to 99+ % by multiple crystallizations and/or distillation.

B. Polymerization of p-dioxanone

Highly purified p-dioxanone is polymerized in the presence of an organometallic catalyst such as diethyl zinc or zirconium acetylacetonate to obtain high molecular weight, fiber forming polymers according to the following typical procedure.

0.1 M (10.2 g) of dry, 99+ % pure p-dioxanone monomer is weighed into a dry flask under an inert atmosphere of dry nitrogen and 0.36 ml of 0.138M diethyl zinc in heptane are added. The monomer to catalyst ratio is calculated as 2000 : 1. After completely mixing the catalyst and monomer, the flask is swirled at intervals over a period of about one hour or less at room temperature until initiation and polymerization is evident by the occurrence of gelation. The flask is then connected to a vacuum of about 14 inches of Hg. The sealed flask is maintained at 80° C in a constant temperature bath for about 72 hours to complete the polymerization. The resulting polymer is characterized by an inherent viscosity I.V. of 0.70 measured on a 0.1% solution of polymer in tetrachloroethane at 25° C, a glass transition temperature T_g of -16° C, a melting temperature T_m of 110° C, and a crystallinity of 37 percent.

In the polymerization procedure, the initial one hour hold time for polymerization initiation is required only when using volatile catalysts which would be lost if the polymerization mixture was immediately placed under vacuum. When nonvolatile catalysts such as zirconium acetyl acetonate are used, this hold time may be omitted and the polymerization reaction mixture placed under vacuum immediately following addition and mixing of catalyst. As a further alternative, the entire polymeriza-

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tion reaction may be conducted under an inert atmosphere at atmospheric pressure.

C. Polymer Extrusion

The polymer obtained in the preceding step is thoroughly dried and melt extruded through a spinnerette using conventional textile fiber spinning procedures to obtain one or more continuous monofilament fibers suitable for use as synthetic absorbable sutures. The spun filaments are drawn about 5x at a temperature of about 43° C to increase molecular orientation and enhance physical properties, particularly tensile strength. The drawn monofilaments having a diameter of about 11 mils corresponding to a size 2-0 suture are characterized by an inherent viscosity of 0.64, a crystallinity of 30 percent, a straight tensile strength of 36,600 psi, an elongation of 99.4 percent, and a knot strength of 31,900 psi.

EXAMPLE II

The method of Example I was repeated using 0.13 ml of zirconium acetyl acetate catalyst (7500 : 1 monomer to catalyst ratio) in the polymerization reaction. Properties of polymer and fiber were as follows:

Polymer

I.V.: 0.71
Tg: -16° C
Tm: 111° C
Crystallinity: 49%

Fiber

I.V.: 0.57
Tensile Strength: 38,600 psi
Elongation: 88.5 percent
Knot Strength: 32,300 psi

EXAMPLE III

Polydioxanone polymers were prepared in accordance with the polymerization method of Example I using 0.20 ml of zirconium acetyl acetate catalyst (5000 : 1 monomer to catalyst ratio) and a polymerization temperature of 90° C. Polymer properties were as follows:

I.V.: 0.65
Tg: -19° C
Tm: 109° C
Crystallinity: 35%

EXAMPLE IV

The method of Example III was repeated using 0.50 ml of zirconium acetylacetate catalyst. (2000 : 1 monomer to catalyst ratio). Polymer properties were as follows:

I.V.: 0.59
Tg: -17° C
Tm: 111° C
Crystallinity: 44%

EXAMPLE V

The method of Example I was repeated at a monomer to catalyst ratio of 4000 : 1 and with a polymerization reaction of three days at 80° C. The resulting polymer had an inherent viscosity of 0.86 and crystallinity of 30 percent. Fibers extruded from the polymer and drawn 6x at 87° C had a diameter of 9 mils, a straight tensile strength of 65,100 psi, elongation of 47.6%, and knot strength of 46,400 psi.

EXAMPLE VI

The method of Example I was repeated using tetraoctylene glycol titanate as the polymerization catalyst. The monomer to catalyst ratio was 12,300 : 1 based on titanium content, and the polymerization reaction was maintained at 80° C for six days. The resulting polymer had an inherent viscosity of 0.86 and a crystallinity of 33 percent. Extruded filaments drawn 6x at 83° C had a diameter of 11 mils, a tensile strength of 55,600 psi, a dry knot strength of 48,800 psi, and a Young's modulus of 167,000 psi.

EXAMPLE VII

Two lots of polydioxanone were prepared according to the method of Example VI using a monomer to catalyst ratio of 26,700 : 1 and with a polymerization reaction of six days and 12 days. The resulting polymers had inherent viscosities of 0.81 and 0.84 respectively. The polymers were combined and extruded into fiber which, after drawing 6x, had the following physical properties.

Fiber Diameter: 9 mils
Tensile Strength: 70,600 psi
Elongation: 46.3

Dry Knot Strength: 50,300 psi

The monofilament fibers had a high degree of softness and pliability.

EXAMPLE VIII

In Vivo Absorption

Two 2 cm segments of monofilament fiber from Example I having a diameter corresponding to size 2-0 suture were implanted aseptically into the left gluteal muscles of 24 female Long Evans rats. The implant sites were recovered after periods of 60, 90, 120 and 180 days and examined microscopically to determine the extent of absorption.

After 60 days the suture cross sections were still transparent and intact. The tissue reactions were slight and most sutures were encapsulated with fibrous tissue. The sutures at this period remained birefringent under polarized light.

At 90 days the sutures were becoming translucent and had lost some of their birefringent properties. A few of the suture cross sections stained pink (eosinophilic) around the periphery and the edges were indistinct, indicating the onset of absorption. The tissue reactions generally consisted of a fibrous capsule and a layer of macrophages interposed between it and the suture surface.

At 120 days the sutures were translucent, most cross sections had taken on an eosinophilic stain, and the sutures appeared to be in the process of active absorption. The tissue reactions consisted of an outer layer of fibroblasts with an interface of macrophages several cell layers thick. Absorption at 120 days was estimated to be approximately 70 percent complete.

At 180 days, absorption of the suture was substantially complete. The incision healed with minimal adverse tissue reaction.

EXAMPLE IX

In Vivo Strength Retention

Segments of the sutures of several Examples were implanted in the posterior dorsal subcutis of female Long Evans rats for periods of 14, 21 and 28 days. The

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sutures were recovered at the designated periods and tested for straight tensile strength with the following results.

Test	Fiber	Implantation Time Days	Tensile Strength Pounds	Strength Retention %
a)	EX. I -	0	3.37	—
		14	1.46	43.4
		21	1.14	33.8
		28	—	—
b)	EX. I - (Sterilized) ¹	0	3.08	—
		14	1.16	37.6
		21	0.97	31.4
		28	0.70	22.9
c)	EX. VI - (Unannealed)	0	3.47	—
		14	2.27	65.3
		21	1.62	46.7
		28	1.53	44.1
d)	EX. VI - (Annealed) ²	0	6.47	—
		14	5.39	83.3
		21	4.87	75.3
		28	4.30	66.5
e)	EX. VI - (Annealed) ^{2,3}	0	3.82	—
		14	2.07	54.0
		21	1.36	35.5
		28	0.68	17.8
f)	EX. V - (Sterilized) ¹	0	4.05	—
		14	2.77	68.4
		21	2.40	59.3
		28	2.15	53.2
g)	EX. V - (Sterilized) ³	0	3.45	—
		14	2.11	61.3
		21	1.36	39.3
		28	0.92	26.6

¹Sterilized with ethylene oxide at 30° C.

²Annealed under nitrogen 24 hours at 65° C.

³Sterilized with cobalt 60.

EXAMPLE X

Small quantities of polydioxanone polymer were prepared in accordance with the general method of Example I using chromatographically pure p-dioxanone monomer and diethyl zinc and tetraoctylene glycol titanate as catalysts. Polymer prepared with diethyl zinc catalyst at a monomer to catalyst ratio of 4,000 and with a polymerization reaction of three days at 80° C had an inherent viscosity of 1.18. Polymer prepared with tetraoctylene glycol titanate catalyst at a monomer to catalyst ratio of 12,250 and with a polymerization reaction of 6 days at 80° C had an inherent viscosity of 1.15. A second batch of high purity p-dioxanone monomer twice distilled in an annular still under a vacuum of 0.10–0.15 mm Hg was polymerized in the presence of tetraoctylene glycol titanate catalyst at a monomer to catalyst ratio of 13,300 and at 80° C for 6 days. The resulting polymer had an inherent viscosity of 2.26.

EXAMPLE XI

Preparation of Methyl-p-Dioxanone

Following the general procedure of Example I., metallic sodium was dissolved in a large excess of 1,2-propane diol and chloroacetic acid was added at 110°–115° C. Excess diol was removed by distillation and the sodium salt of the hydroxy acid converted to free acid by the addition of water and hydrochloric acid. Sodium chloride was precipitated by the addition of ethanol and removed by filtration. The resulting product was distilled in the presence of M_2CO_3 to remove excess alcohol and water and to recover crude methyl dioxanone monomer as a distillate at 196° to 202° C. After purification, the monomer can be polymerized and extruded to form fibers suitable for use as absorbable sutures as described in Example I.

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EXAMPLE XII

Preparation of Dimethyl-p-Dioxanone

The procedure of Example XI was repeated reacting metallic sodium with 2,3-butanediol and chloroacetic acid at about 130° C. Crude dimethyl dioxanone monomer was recovered from the distillation at 190° to 213° C. After purification the monomer can be polymerized and extruded to form fibers suitable for use as absorbable sutures as described in Example I.

EXAMPLE XIII

Preparation of 1,4-dioxepan-2-one

The procedure of Example VI was repeated reacting metallic sodium with 1,3-propane diol and chloroacetic acid. Crude 1,4-dioxepan-2-one monomer was recovered from the distillation at 300° to 310° C. After purification, the monomer can be polymerized and extruded to form fibers suitable for use as absorbable sutures as described in Example I.

We have discovered that exceptionally high purity of p-dioxanone monomer is required to obtain polymers having a sufficiently high inherent viscosity to yield strong fibers upon extrusion. In general, the monomers are purified to 99+ % by distillation and recrystallization prior to polymerization, and the resulting polymers have an inherent viscosity of at least about 0.50, and preferably 0.80 or higher measured as above described. As illustrated in Example X, polymers prepared from highly purified dioxanone have inherent viscosities well in excess of 1.10.

Drawn fibers of polydioxanone possess an unique combination of desirable properties. In particular, the monofilament fibers combine high tensile strength and knot strength with a pliability not to be found in any previous absorbable suture material, natural or synthetic. For example, the Young's modulus of the polydioxanone fiber of Example VI was 167,200 psi. In comparison, the Young's modulus for monofilament polyglycolide fibers and for 90/10 glycolide/lactide copolymer fibers is about 1 – 2 million psi, while that for moist catgut is about 350,000 psi. The low Young's modulus of polydioxanone makes this fiber particularly well suited for use as an absorbable monofilament suture, whereas prior synthetic absorbable sutures have largely been limited to braided, multifilament constructions which tend to be softer and more flexible than corresponding sizes of monofilament material. Monofilamented sutures are, of course, preferred for use in many surgical applications such as in ophthalmic procedures where smoothness of the suture surface is of particular importance.

The polymers of p-dioxanone of the present invention are also unique as compared with prior synthetic absorbable materials in that the sutures of these polymers can be sterilized by cobalt 60 radiation as well as by ethylene oxide. As illustrated in Example IX, while cobalt 60 sterilization results in some reduction in fiber strength and some increase in the in vivo rate of strength loss, the sterilized fiber nevertheless retains sufficient strength initially and for 28 days in vivo to make the fiber suitable for use in surgical procedures.

While the preceding examples have been directed to the preparation of homopolymers of p-dioxanone, methyl dioxanone, dimethyl dioxanone, and 1,4-dioxepan-2-one, these examples are for purposes of illustration only and are not limiting of the invention. Mixtures

of these polymers, copolymers of two or more of the above enumerated monomers, and copolymers of these monomers with up to about 50% by weight of other copolymerizable monomers which produce non-toxic and absorbable polymers are likewise included within the present invention. For example, such copolymers of dioxanone with lactide and/or glycolide are useful in the preparation of absorbable sutures, and the physical and chemical properties of such sutures such as strength, stiffness, and rate of absorption can be controlled by varying the relative proportions of the monomer constituents. In addition, the copolymers may be prepared by random, block or graft polymerization techniques in order to obtain particular combinations of compositions and physical and chemical properties. In certain applications where the rate of absorption of polydioxanone is less than desired, copolymers of dioxanone with from about 5 to 25 percent or more glycolide having a faster rate of absorption may be preferred.

It is to be understood that inert additives such as coloring materials and plasticizers can be incorporated in the sutures. Any of a variety of plasticizers such as, for instance, glyceryl triacetate, ethyl benzoate, diethyl phthalate, dibutyl phthalate and bis 2-methoxyethyl phthalate can be used if desired. The amount of plasticizer may vary from 1 to about 20 percent or more based on the weight of the polymer. Not only does the plasticizer render the filaments even more pliable, but it also helps in spinning. As used herein, the term "inert" means materials that are chemically inert to the polymer, and biologically inert to living tissue, i.e., do not cause any of the adverse effects previously discussed.

Filaments of the present invention are adversely affected by moisture and are accordingly preferably packaged in a substantially moisture free environment and in hermetically sealed packages, a preferred form of which is shown in FIG. 2. In FIG. 2, there is shown a suture package 14 having disposed therein a coil of suture 12, one end of which is attached to needle 13. The needle and suture are positioned within a cavity 16 that is evacuated or filled with a dry atmosphere such as air or nitrogen. The package is fabricated of two sheets of aluminum foil or an aluminum foil-plastic laminate and heat sealed or bonded with adhesive at the skirt 16 to hermetically seal the cavity and isolate the contents of the package from the external atmosphere.

Filaments of the present invention may be used as monofilament or multifilament sutures, or may be woven, braided, or knitted either alone or in combination with absorbable fibers such as polyglycolide or poly (lactide-co-glycolide), or with non-absorbable fibers such as nylon, polypropylene, polyethyleneterephthalate, or polytetrafluoroethylene to form multifilament sutures and tubular structures having use in the surgical repair of arteries, veins, ducts, esophagi and the like.

Multifilament yarns that contain polymer filaments of the present invention together with nonabsorbable filaments are illustrated in FIG. 4 wherein the nonabsorbable fiber is represented by the hatched fiber cross section 19. In FIG. 4, the fibers 20 are extruded from homopolymer or copolymer compositions of the present invention as described above. The relative proportions of absorbable filaments 20 and nonabsorbable filaments 19 may be varied to obtain the absorption characteristic desired in the woven fabric or tubular implants. Methods of weaving and crimping vascular prostheses are described in U.S. Pat. 3,096,560.

Composite fabrics of absorbable and nonabsorbable materials fashioned by textile processes including weaving, knitting, and fabricating by the nonwoven felting of fibers are described in U.S. Pat. No. 3,108,357 and U.S. Pat. No. 3,463,158. Similar techniques may be used in the manufacture of surgical aids wherein nonabsorbable fibers are combined with absorbable fibers composed of the polymers of this invention. The surgical utility of "bicomponent filaments" containing absorbable and nonabsorbable components is described in U.S. Pat. No. 3,463,158, the teaching of which is incorporated herein by reference. Monofilaments of the polymers of the present invention may be woven or knitted to form an absorbable fabric having the structure illustrated in FIG. 5, useful surgically in hernia repair and in supporting damaged liver, kidney, and other internal organs.

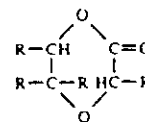
The products of the invention are useful in surgical applications where an absorbable aid or support is required, as for example, in the formation of surgical mesh, absorbable staples, artificial tendons, or cartilage material, and in other uses where a temporary aid during healing is needed. They may also be used to advantage in repairing hernias and in anchoring organs which have become loose.

The polymers of the present invention are also useful in the manufacture of cast films and other solid surgical aids such as scleral buckling prostheses. Thus, cylindrical pins, screws as illustrated in FIG. 3, reinforcing plates, etc., may be machined from the cast polymer having in vivo absorption characteristics depending upon the polymer composition and molecular weight.

Many different embodiments of this invention will be apparent to those skilled in the art and may be made without departing from the spirit and scope thereof. It is accordingly understood that this invention is not limited to the specific embodiments thereof except as defined in the appended claims.

We claim:

1. A sterile, synthetic absorbable suture comprising oriented fiber of a polymer of a monomer having the formula:



wherein R' and R are individually hydrogen, methyl or ethyl, said suture being dry to the extent of being substantially free of moisture, and characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strength of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

2. A suture of claim 1 wherein R and R' are hydrogen and the monomer is p-dioxanone.

3. A suture of claim 2 wherein said polymer is characterized by an inherent viscosity greater than about 0.50 measured as 0.1% solution of polymer in tetrachloroethane at 25° C.

4. A suture of claim 3 comprising a homopolymer of p-dioxanone.

5. A suture of claim 1 comprising a polymer of methyl-p-dioxanone.

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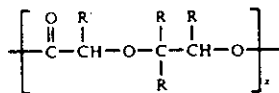
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6. A suture of claim 1 comprising a polymer of dimethyl-p-dioxanone.

7. A suture of claim 1 comprising a copolymer of more than 50% by weight p-dioxanone and less than 50% by weight of at least one other monomer copolymerizable with p-dioxanone to an absorbable polymer.

8. A suture of claim 7 wherein said copolymer is of p-dioxanone and glycolide or lactide.

9. A sterile synthetic absorbable suture comprising oriented fiber of a polymer having units of the formula:



wherein R' and R are individually hydrogen, methyl, or ethyl and x is the degree of polymerization resulting in a fiber forming polymer, said suture being dry to the extent of being substantially free of moisture, and characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strength of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

10. A suture of claim 9 wherein said polymer is a homopolymer of p-dioxanone having an inherent viscosity of at least 0.50 in a 0.1% solution of tetrachloroethane at 25° C.

11. A suture of claim 10 wherein the inherent viscosity of said polymer is at least 0.80.

12. A suture of claim 9 wherein said polymer is a copolymer of more than 50% by weight p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

13. A suture of claim 12 wherein said polymer is a copolymer of p-dioxanone and lactide or glycolide.

14. A suture of claim 9 wherein said polymer is a homopolymer of methyl-p-dioxanone or copolymer of more than 50% by weight methyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

15. A suture of claim 9 wherein said polymer is a homopolymer of dimethyl-p-dioxanone or copolymer of more than 50% by weight dimethyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

16. A suture of claim 1 having a surgical needle attached to at least one end thereof.

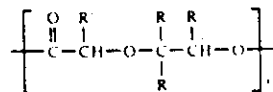
17. A needle and suture combination of claim 16 packaged in a sterile and dry environment within a hermetically sealed and substantially moisture impervious container.

18. A suture of claim 9 having a surgical needle attached to at least one end thereof.

19. A needle and suture combination of claim 18 packaged in a sterile and dry environment within a hermetically sealed and substantially moisture impervious container.

20. A surgical prosthesis comprising a fabric manufactured at least in part from synthetic absorbable fibers of a polymer having units of the formula:

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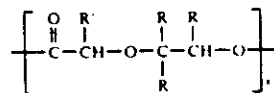
wherein R' and R are individually hydrogen, methyl, or ethyl and x is the degree of polymerization resulting in a fiber forming polymer, said fibers being dry to the extent of being substantially free of moisture, and characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strength of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

21. A surgical prosthesis of claim 20 wherein said polymer is a homopolymer of p-dioxanone or a copolymer of more than 50% by weight p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

22. A surgical prosthesis of claim 20 wherein said polymer is a homopolymer of methyl-p-dioxanone or a copolymer of more than 50% by weight methyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

23. A surgical prosthesis of claim 20 wherein said polymer is a homopolymer of dimethyl-p-dioxanone or a copolymer of more than 50% by weight dimethyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

24. A surgical prosthesis comprising a solid surgical aid formed from an absorbable polymer having units of the formula:



wherein R' and R are individually hydrogen, methyl, or ethyl and x is the degree of polymerization resulting in a fiber forming polymer, said prosthesis being dry to the extent of being substantially free of moisture.

25. A surgical prosthesis of claim 24 wherein said polymer is a homopolymer of p-dioxanone having an inherent viscosity of at least 0.50 in a 0.1% solution of tetrachloroethane at 25° C.

26. A surgical prosthesis of claim 24 wherein said polymer is a copolymer of at least 50% by weight p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

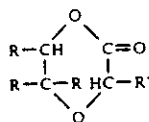
27. A surgical prosthesis of claim 24 wherein said polymer is a homopolymer of methyl-p-dioxanone or a copolymer of more than 50% by weight methyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

28. A surgical prosthesis of claim 24 wherein said polymer is a homopolymer of dimethyl-p-dioxanone or a copolymer of more than 50% by weight dimethyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

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29. A method of closing a wound in living tissue which comprises approximating the edges of the wound with a synthetic absorbable suture consisting of at least one filament of a polymer of a monomer having the formula:



wherein R' and R are individually hydrogen, methyl or ethyl, said suture being at least partially embedded in the living tissue, and leaving said suture in said tissue until the embedded suture is absorbed during the healing process, said suture being characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strength of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

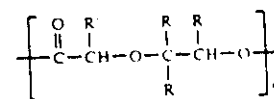
30. A method of claim 29 wherein R and R' are hydrogen and the monomer is p-dioxanone.

31. A method of claim 29 wherein the monomer is methyl-p-dioxanone.

32. A method of claim 29 wherein the monomer is dimethyl-p-dioxanone.

33. A method of closing a wound in living tissue which comprises approximating the edge of the wound with a synthetic absorbable suture consisting of at least one filament of a polymer having units of the formula:

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wherein R' and R are individually hydrogen, methyl or ethyl, and x is the degree of polymerization resulting in a fiber forming polymer, said suture being at least partially embedded in the living tissue, and leaving said suture in said tissue until the embedded suture is absorbed during the healing process, said suture being characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strength of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

34. A method of claim 33 wherein said polymer is a homopolymer of p-dioxanone having an inherent viscosity of at least 0.50 in a 0.1 percent solution of tetrachloroethane at 25° C.

35. A method of claim 34 wherein the inherent viscosity of said polymer is at least 0.80.

36. A method of claim 33 wherein said polymer is a copolymer of more than 50% by weight p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

37. A method of claim 36 wherein said polymer is a copolymer of p-dioxanone and lactide or glycolide.

38. A method of claim 33 wherein said polymer is a homopolymer of methyl-p-dioxanone or a copolymer of more than 50% by weight methyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

39. A method of claim 33 wherein said polymer is a homopolymer of dimethyl-p-dioxanone or a copolymer of more than 50% by weight dimethyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

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United States Patent [19][11] **Patent Number:** 5,147,400

Kaplan et al.

[45] **Date of Patent:** Sep. 15, 1992[54] **CONNECTIVE TISSUE PROSTHESIS**[75] **Inventors:** Donald S. Kaplan, Weston; John Kennedy, Stratford; Ross R. Muth, Brookfield, all of Conn.[73] **Assignee:** United States Surgical Corporation, Norwalk, Conn.[21] **Appl. No.:** 581,462[22] **Filed:** Sep. 12, 1990**Related U.S. Application Data**

[63] Continuation-in-part of Ser. No. 349,648, May 10, 1989, Pat. No. 4,990,158.

[51] **Int. Cl.⁵** A61F 2/08[52] **U.S. Cl.** 623/13; 623/1; 623/11; 623/66[58] **Field of Search** 623/1, 13, 11[56] **References Cited****U.S. PATENT DOCUMENTS**

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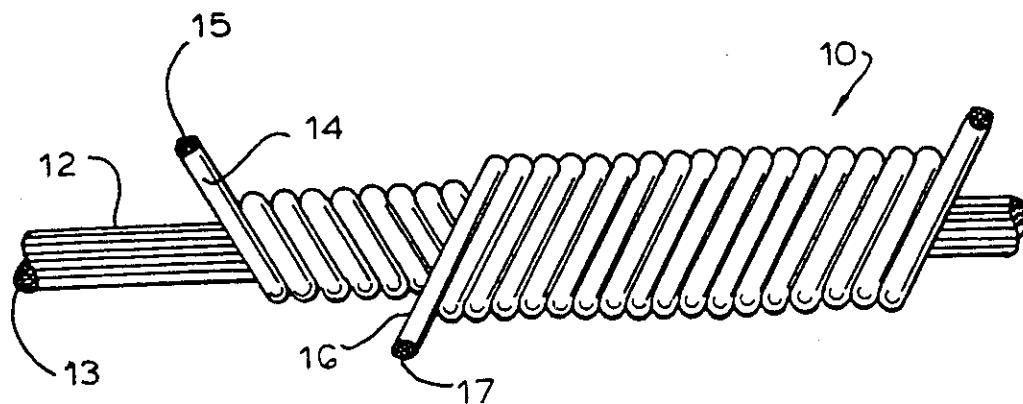
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Primary Examiner—David Isabella
Assistant Examiner—Debra S. Brittingham
Attorney, Agent, or Firm—Thomas R. Bremer; Peter G. Dilworth; Rocco S. Barrese

[57] **ABSTRACT**

A semi-bioabsorbable connective tissue prosthesis, e.g., a replacement for the human anterior cruciate ligament, is provided whose stress-strain characteristics closely match those of the natural tissue.

58 Claims, 5 Drawing Sheets



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C.A. No. 04-12457 PBS

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FIG. 1

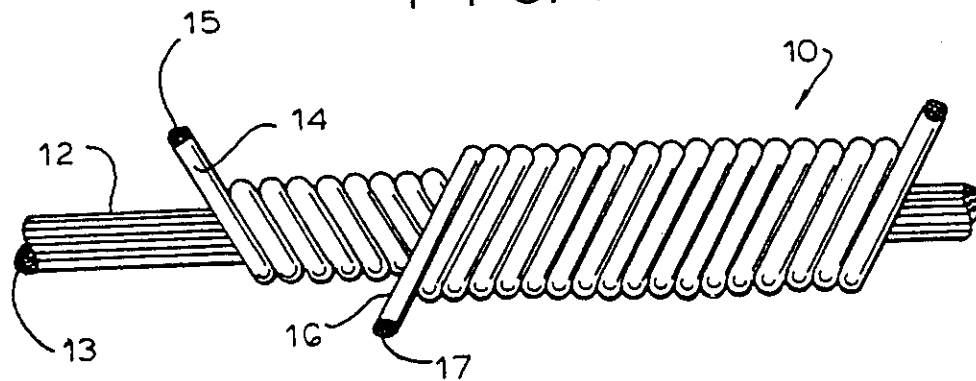


FIG. 2

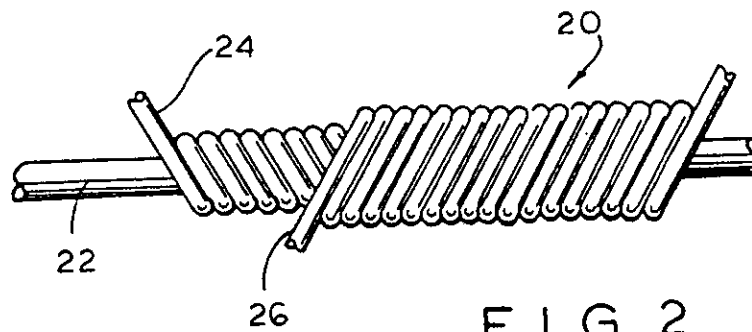
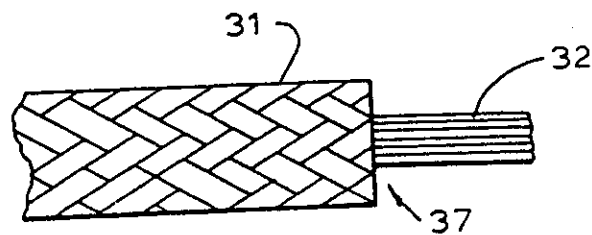
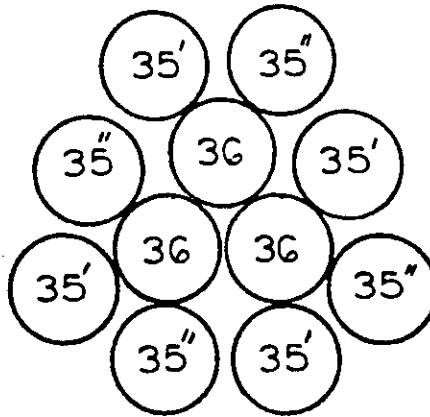
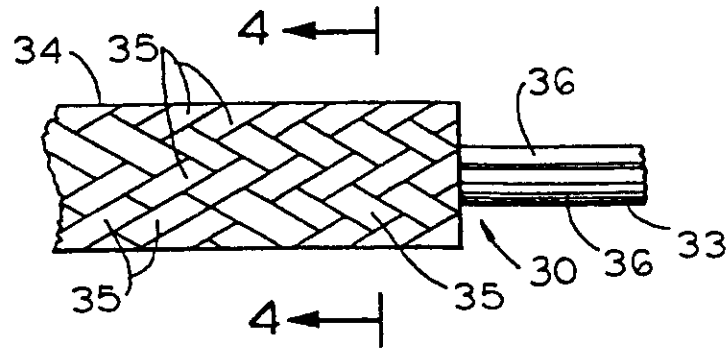


FIG. 5



F I G. 3



F I G. 4

FIG. 6

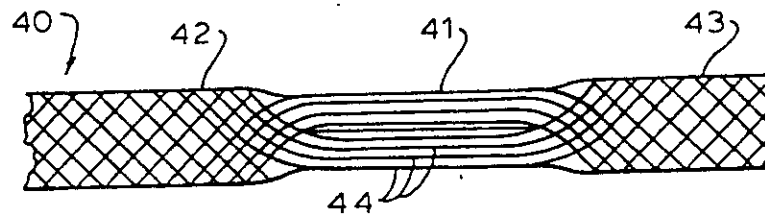
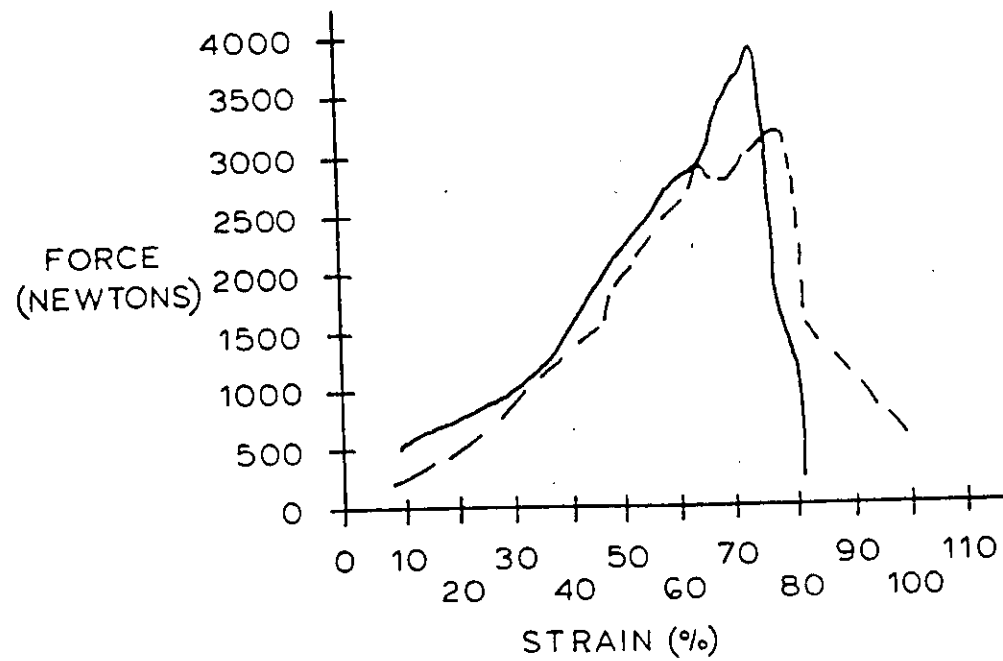


FIG. 7

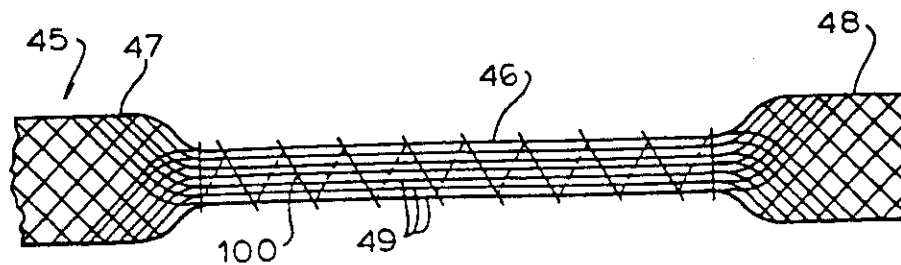


FIG. 8

FIG. 9

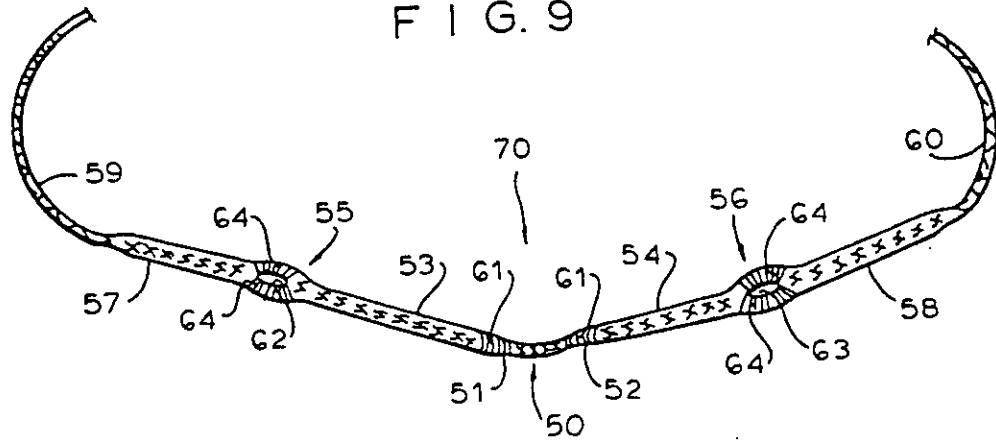


FIG. 10

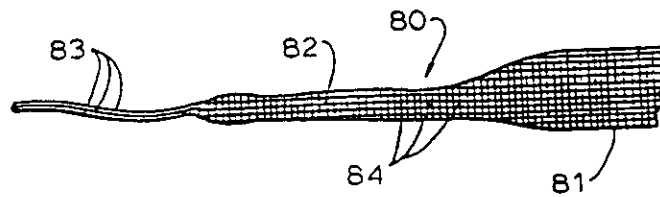
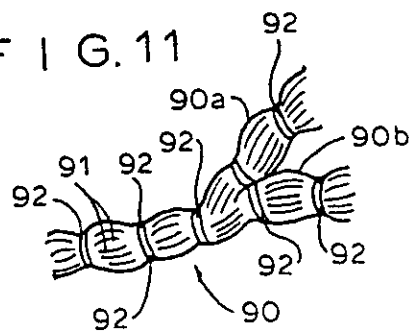


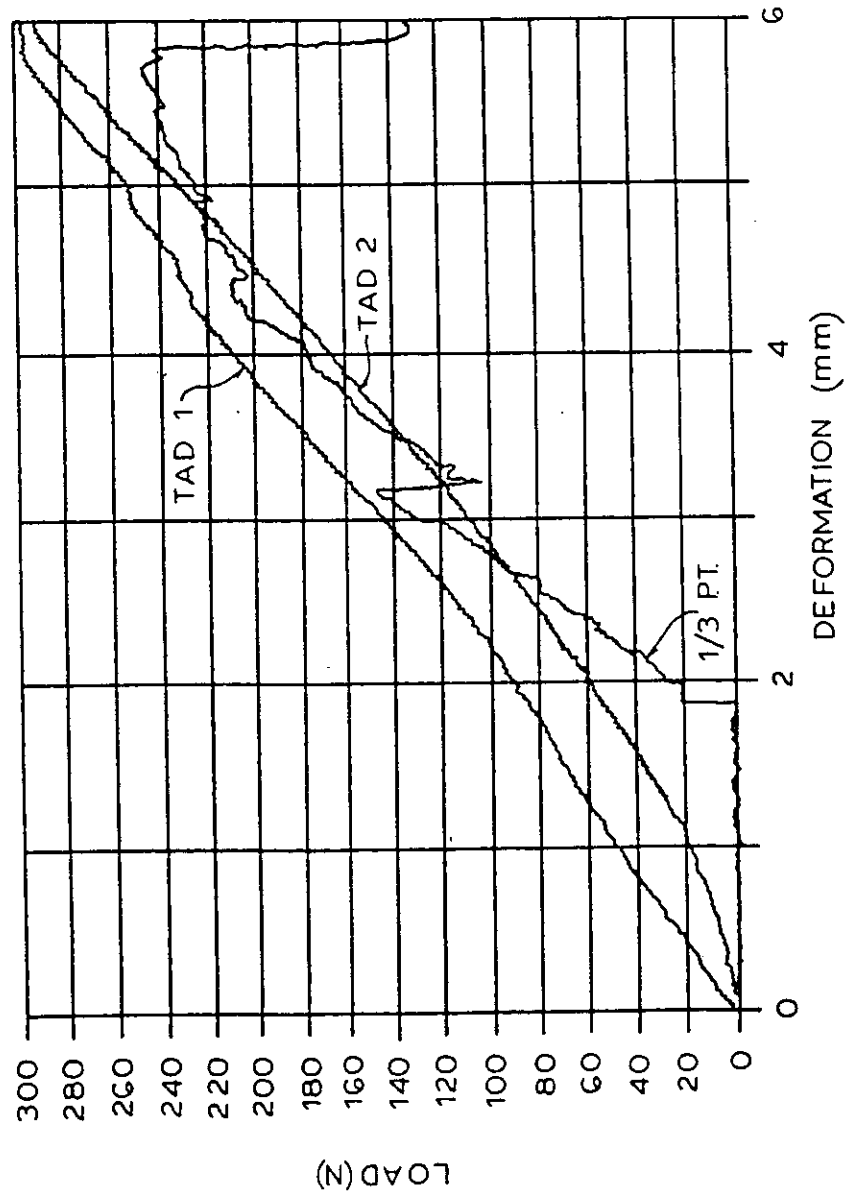
FIG. 11



F I G. 12

TENSILE TESTS

100 % sec.



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CONNECTIVE TISSUE PROSTHESIS

CROSS REFERENCE TO RELATED APPLICATION

The application is a continuation-in-part of commonly assigned, co-pending U.S. patent application Ser. No. 349,648, filed May 10, 1989, now U.S. Pat. No. 4,990,158.

BACKGROUND OF THE INVENTION

This invention relates to a connective tissue prosthesis and, in particular, to a biocompatible ligament or tendon prosthesis which closely approximates the biomechanical characteristics of the natural tissue to be replaced or augmented.

Numerous connective tissue materials and constructions have been proposed for use as temporary or permanent grafts in ligament and tendon repair. Feagin, Jr., Ed., *The Crucial Ligaments/Diagnosis and Treatment of Ligamentous Injuries About the Knee* (Churchill Livingstone, N.Y., 1988) describes a number of partially bioabsorbable materials which have been investigated for use as ligament grafts. In Chapter 33 of this publication (Rodkey, "Laboratory Studies of Biodegradable materials for Cruciate Ligament Reconstruction"), it is reported that while a 100 percent biodegradable ligament fabricated from polyglycolic acid (PGA) was found to be safe, strong, well-tolerated and provided stability for the repaired anterior cruciate ligament in dogs, its complete resorption within five weeks makes it unsuitable for use in prostheses intended for humans since a human ligament prosthesis must provide support over a much longer period of time. It is further reported that a study in dogs of the intraarticular use of a partially biodegradable ligament prosthesis possessing a Dacron (i.e., DuPont's polyethylene terephthalate (PET)) and PGA core and a separate outer sleeve woven from PGA and Dacron of a different percentage of composition gave disappointing results.

U.S. Pat. Nos. 4,792,336 and 4,942,875 describe a surgical device for repairing or augmenting connective tissue and comprising a plurality of fibers, in which the majority of the fibers are in a direction essentially parallel to the length of the device and can be either 100 percent bioabsorbable or can contain a nonabsorbable component. Additionally, sleeve yarns consisting completely of absorbable material wrap around these axial or warp yarns.

Biomedical Business International Report No. 7041 (Second Revision, May 1986), "Orthopaedic and Diagnostic Devices", pages 5—5 to 5-12, identifies a variety of materials which have been used in the fabrication of prosthetic ligaments including carbon fiber, expanded Teflon (i.e., DuPont's polytetrafluoroethylene), a combination of silicone and PET, polypropylene, polyethylene, nickel-chromium alloy fibers individually enclosed in synthetic textile or natural silk, carbon material coated with gelatin, polyester combined with PET fibers, bovine tissues, and others.

Other disclosures of ligament and tendon repair devices are provided, inter alia, in U.S. Pat. Nos. 3,805,300; 4,187,558; 4,301,551; 4,483,023; 4,584,722; 4,610,688; 4,668,233; 4,775,380; 4,788,979; and PCT Patent Publication No. WO 89/01320.

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Chapter 33 (page 540) of the Feagin, Jr. publication referred to above identifies the characteristics of an ideal ligament prosthesis as follows:

- (1) it must be durable with adequate strength to withstand the extreme forces placed upon it, yet compliant enough to allow for repetitive motion without failure or excessive creep elongation;
- (2) it must be tolerated by the host with no antigenic or carcinogenic reaction;
- (3) if partially or completely biodegradable, the size of the individual fibers and the construction pattern must be appropriate to support and allow eventual reconstitution of the repaired structure with ingrowth of fibrous tissue that matures to normal or near normal collagen;
- (4) it must tolerate sterilization and storage; and
- (5) it should be easily implanted using surgical and potentially arthroscopic techniques.

The existence of so many different types of materials and devices for use in connective tissue repair, some of which have been identified above, bears testimony to the difficulty of meeting some, much less all, of the foregoing characteristics in a single prosthetic device.

SUMMARY OF THE INVENTION

It is a principal object of the invention to provide a semi-bioabsorbable or fully bioabsorbable connective tissue prosthesis, e.g., a ligament or tendon repair device, which exhibits the stress-strain properties of the natural tissue to be replaced or augmented.

It is a specific object of the invention to provide the foregoing connective tissue prosthesis as a structure formed from a composite yarn comprising a non-bioabsorbable core yarn surrounded by a bioabsorbable or semi-bioabsorbable cover or sheath yarn.

It is a further specific object of the invention to provide a connective tissue prosthesis formed from a composite yarn wherein an elastic core yarn is wrapped with a relatively inelastic, bioabsorbable or semi-bioabsorbable sheath yarn, so as to exhibit the stress-strain properties of natural tissue.

It is another specific object of the invention to provide a prosthetic replacement for a human anterior cruciate ligament which is based on the aforesaid structure, in particular, one fabricated from a yarn whose sheath yarn component is derived from a glycolide-lactide copolymer.

In keeping with these and other objects of the invention, there is provided a connective tissue prosthesis comprising:

- (a) a core made up of a first biocompatible composite yarn extending in the lengthwise direction; and
- (b) a sheath surrounding the core and fabricated from a second biocompatible yarn,

wherein the first composite yarn in the core (a) comprises a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, bioabsorbable or semi-bioabsorbable sheath yarn component.

The second biocompatible yarn forming the sheath (b) may be the same as, or different from, the first composite yarn which forms the core (a). More specifically, the second biocompatible yarn may also comprise a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, bioabsorbable or semi-bioabsorbable sheath yarn component.

Also in keeping with the above and other objects of the invention, a connective tissue prosthesis is provided which comprises a tubular component fabricated from

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composite yarn, the yarn comprising a biocompatible, nonbioabsorbable core yarn component surrounded by a biocompatible, bioabsorbable or semi-bioabsorbable sheath yarn component.

The foregoing connective tissue prostheses meet the Feagin, Jr. criteria, identified supra, to a surprising degree. Due to elasticity of the composite yarn core component and relative inelasticity of the composite yarn sheath component, the stress-strain characteristics of the connective tissue prostheses closely match those of the natural tissue which they replace and their resorption properties can be calibrated to maintain the functionality of the prostheses throughout the entire period of the tissue regeneration process. The prostheses of this invention are readily sterilizable, possess good storage stability when suitably protected from hydrolytic forces, and can be installed at a ligament, tendon, vascular, or tracheal repair site employing known surgical reconstruction techniques.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1 and 2 are enlarged isometric views of composite yarns which are utilized in the construction of the connective tissue prosthesis herein;

FIG. 3 is an enlarged isometric view of an alternative composite yarn utilized in the construction of the connective tissue prosthesis herein;

FIG. 4 is a schematic, cross-sectional view along line 4-4 of FIG. 3;

FIG. 5 represents a section of a ligament prosthesis manufactured from the composite yarn of FIG. 1 and suitable for use in the surgical reconstruction of the human anterior cruciate ligament;

FIG. 6 is a plot of experimental data showing the stress-strain characteristics of the prosthesis of FIG. 5 compared with the stress-strain characteristics of a natural ligament as reported in the literature;

FIG. 7 represents a section of a tubular ligament prosthesis manufactured from the composite yarn of the present invention and having an unbraided center section;

FIG. 8 represents a section of a tubular ligament prosthesis similar to FIG. 7 and additionally having the unbraided center section helically wrapped with a yarn;

FIG. 9 represents a section of a braided prosthesis manufactured from composite yarn of the present invention and modified in various fashion over the length thereof;

FIG. 10 represents a section of a tubular braided prosthesis manufactured from composite yarn of the present invention and provided with threading means;

FIG. 11 represents a section of a prosthesis manufactured from composite yarn of the present invention in which the prosthesis is branched; and

FIG. 12 is a plot of experimental data showing the stress-strain characteristics of the prosthesis of FIG. 7 compared with a canine patellar tendon.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in FIG. 1, composite yarn 10 comprises a core yarn component 12 made up of a multiplicity of individual biocompatible, essentially non-bioabsorbable and preferably elastic filaments 13, advantageously provided with a slight to moderate twist, and a sheath yarn component 14 made up of a multiplicity of individual biocompatible, bioabsorbable or semi-bioabsorbable and preferably relatively inelastic filaments 15 wound in a

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first direction around the core and an external multifilamentous sheath yarn component 16, also made up of individual biocompatible, bioabsorbable or semi-bioabsorbable and preferably relatively inelastic filaments 17, wound in a second and opposite direction around sheath yarn component 14. For example, multifilamentous sheath yarn component 16 may comprise both absorbable and non-absorbable filaments 17. Generally, the filaments 13 of core yarn component 12 are substantially parallel.

Non-bioabsorbable core yarn component 12 functions to impart elasticity to composite yarn 10 and acts as a scaffolding during and after absorption of the bioabsorbable sheath. Bioabsorbable sheath yarn components 14 and 16 function to provide the composite yarn with relative inelasticity, tensile strength, and absorption characteristics which allow for desirable tissue ingrowth and incorporation of the composite yarn into the body structure. Sheath yarn components 14 and 16 each have a lengthwise axis which is non-perpendicular to the lengthwise axis of core component 12. While core yarn component 12 can be wrapped with a single layer of sheath yarn component, the illustrated arrangement of two layers of sheath yarn components 14 and 16 is generally preferred as this construction helps to give composite yarn 10 a balanced structure which resists crimping or kinking when used in the manufacture of a prosthesis such as shown in FIGS. 5 and 7-11.

Where, as shown in the embodiment of FIG. 1, at least two sheath yarn components are employed in the construction of the composite yarn, the composition, number and denier of the individual filaments, and braiding (if any) of these yarn components as well as their relative rates of bioabsorption can differ. For example, non-absorbable filaments may be combined with absorbable filaments to provide one or more semi-absorbable sheath yarn components. This capability for differential absorption can be advantageously exploited in a connective tissue prosthetic device in which the outermost sheath yarn component is absorbed by the body at a faster rate than the underlying sheath yarn component, or vice versa, thus resulting in a staged absorption of the sheath components of the composite yarn.

Core yarn component 12 must be essentially non-bioabsorbable, i.e., it must resist degradation when, as part of the connective tissue prosthesis of this invention, it is implanted in a body. The term "non-bioabsorbable" as used herein applies to materials which permanently remain within the body or at least remain in the body for a relatively long period of time, e.g., at least about two years. It is preferred to employ a core yarn material which is also elastic, i.e., a polymeric material which in filamentous form exhibits a relatively high degree of reversible extensibility, e.g., an elongation at break of at least about 30 percent, preferably at least about 40 percent and more preferably at least about 50 percent. Fiber-forming polymers which are both non-bioabsorbable and elastic, and as such preferred for use as the core yarn component herein, include fiber-forming polyolefins such as polyethylene homopolymers, polypropylene homopolymers, ethylene propylene copolymers, ethylene propylene terpolymers, etc., fluorinated hydrocarbons, fluorosilicones, isobutylenes, isoprenes, polyacrylates, polybutadienes, polyurethanes, polyether-polyester copolymers, and the like. Hytrel (DuPont), a family of copolyester elastomers based on (soft) polyether segments and (hard) polyester segments, and span-

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dex, an elastomeric segmented polyurethane, provide especially good results.

Hytrel is manufactured in various commercial grades by DuPont, such as Hytrel 4056, 5526, 5556 and 7246. Hytrel 5556 is especially suitable as the core component 12 of the composite yarn 10 when used to form a vascular graft, while Hytrel 7246 is well-suited for the core component 12 of the composite yarn 10 when used to form a ligament prosthesis or tendon augmentation device.

Several properties of the various Hytrel grades are presented in the table below:

drophilic coatings which are suitable for this purpose include polymeric materials such as the sparingly cross-linked poly(hydroxyethyl methacrylate) hydrogels disclosed in U.S. Pat. Nos. 2,976,576 and 3,220,960; hydrogels based on cross-linked polymers of n-vinyl lactams and alkyl acrylates as disclosed in U.S. Pat. No. 3,532,679; graft copolymers of hydroxyalkyl methacrylate and polyvinylpyrrolidone disclosed in U.S. Pat. No. 3,621,079, and many others.

10 Fiber-forming materials which are relatively inelastic are suitable for providing the sheath yarn component of composite yarn 10 provided such materials are fairly

	Hytrel Grade No. (Injection Molded at 23° C. for Testing)			
	4056	5526	5556	7246
Hardness in durometer points (ASTM Test No. D2240)	40	55	55	72
Flexural Modulus (ASTM Test No. D790)				
at -40° C. in MPa	155	930	930	2,410
at -40° F. in psi	22,500	135,000	135,000	350,000
at 23° C. in MPa	55	207	207	518
at 73° F. in psi	8,000	30,000	30,000	75,000
at 100° C. in MPa	27	110	110	207
at 212° F. in psi	3,900	16,000	16,000	30,000
ASTM Test No. D638				
(i) Tensile Strength at Break.				
MPa	28.0	40.0	40.0	45.8
psi	4050	5800	5800	6650
(ii) Elongation at Break, %	550	500	500	350
(iii) Tensile Stress at 5% Strain.				
MPa	2.4	6.9	6.9	14.0
psi	350	1,000	1,000	2,025
(iv) Tensile Stress at 10% Strain.				
Mpa	3.6	10.3	10.3	20.0
psi	525	1,500	1,500	2,900
Izod Impact (Notched) (ASTM Test No. D256, Method A)				
at -40° C. in J/cm	No Break	No Break	No Break	0.4
at -40° F. in ft-lbf/in	No Break	No Break	No Break	0.8
at 23° C. in J/cm	No Break	No Break	No Break	2.1
at 73° F. in ft-lbf/in	No Break	No Break	No Break	3.9
Resistance to Flex Cut Growth, Ross (Pierced), in Cycles to 100% cut growth (ASTM Test No. D1052)	> 1 × 10 ⁶	> 5 × 10 ⁵	> 5 × 10 ⁵	—
(v) Initial Tear Resistance, Die C (ASTM Test No. D1004)				
in kN/m	101	158	158	200
in lbf/in	580	900	900	1,146
Melt Flow Rate in g/10 min. (ASTM Test No. D1238)	5.3	18	7.0	12.5
Test Conditions: Temperature, °C./Load, Kg	190/2.16	220/2.16	220/2.16	240/2.16
(vi) Melting Point (ASTM Test No. D3418)				
in °C.	148	202	202	219
in °F.	298	396	396	426
Vicat Softening Point (ASTM Test No. D1525)				
in °C.	108	180	180	207
in °F.	226	356	356	405
Specific Gravity (ASTM Test No. D792)	1.16	1.20	1.20	1.25
Water Absorption, 24 hr. in % (ASTM Test No. D570)	0.6	0.5	0.5	0.3

(i)head speed 50 mm/min. or 2 in/min

(ii)head speed 25 mm/min. or 1 in/min

(iii)specimens 1.9 mm or 0.075 in. thick

(iv)differential scanning calorimeter (DSC), peak of endotherm

Corresponding properties of other grades of Hytrel are available from DuPont.

If desired, the core yarn component can be provided with a nonabsorbable hydrophilic coating to improve its wettability by body fluids, e.g., synovial fluid. Hy-

65 rapidly bioabsorbed by the body, e.g., exhibiting a loss of tensile strength in from about 2 to about 26 weeks and total absorption within from about two to about fifty

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two weeks. It is to be understood, however, that the expression "relatively inelastic" does not preclude the presence of some minor degree of elasticity in the sheath yarn component, merely that it excludes a degree of elastic behavior as described in connection with the preferred type of core yarn component.

The sheath yarn component can be woven, braided or knitted in whole or in part and will ordinarily possess a relatively high tensile strength, e.g., a straight tensile strength of at least about 30,000 p.s.i., preferably at least about 60,000 p.s.i. and more preferably at least about 90,000 p.s.i.

Bioabsorbable, relatively inelastic fiber-forming polymers and polymer blends from which the sheath yarn component herein can be formed include those derived at least in part from such monomers as glycolic acid, glycolide, lactic acid, lactide, p-dioxanone, trimethylene carbonate, ε-caprolactone, hydroxycaproic acid, etc., and various combinations of these and related monomers as disclosed, e.g., in U.S. Pat. Nos. 2,668,162; 2,703,316; 2,758,987; 3,225,766; 3,297,033; 3,422,181; 3,531,561; 3,565,077; 3,565,869; 3,620,218; 3,626,948; 3,636,956; 3,736,646; 3,772,420; 3,773,919; 3,792,010; 3,797,499; 3,839,297; 3,867,190; 3,878,284; 3,982,543; 4,047,533; 4,052,988; 4,060,089; 4,137,921; 4,157,437; 4,234,775; 4,237,920; 4,300,565; 4,429,080; 4,441,496; 4,523,591; 4,546,152; 4,559,945; 4,643,191; 4,646,741; 4,653,497; and, 4,741,337; U.K. Patent No. 779,291; D. K. Gilding et al., "Biodegradable polymers for use in surgery—polyglycolide/poly(lactic acid) homo- and copolymers: I", *Polymer*, Volume 20, pages 1459-1464 (1979), and D. F. Williams (ed.), *Biocompatibility of Clinical Implant Materials*, Vol. II, ch. 9: "Biodegradable Polymers" (1981).

Sheath yarn components manufactured from polymers of high lactide or glycolide content, e.g., those in which at least about 75 percent of the monomeric units are derived from either glycolide or lactide, are preferred for the construction of the composite yarn of this invention. Polymers of high glycolide content tend to be absorbed more quickly than those possessing a high lactide content. Accordingly, the glycolide-based polymers may be preferred for the manufacture of a sheath yarn component providing the outermost sheath yarn(s) in a multiple sheath yarn component construction, the underlying internal sheath yarn(s) being manufactured from the more slowly absorbable lactide-based polymers. An especially preferred lactide-glycolide copolymer for forming the sheath yarn component of the composite yarn contains from about 70 to about 90, and preferably from about 75 to about 85 mole percent lactide monomer with the balance being provided by the glycolide monomer. Thus, for example, a sheath yarn component formed from a lactide-glycolide copolymer based on 80 mole percent lactide-20 mole percent glycolide is especially advantageous for constructing the composite yarn, and ultimately, the connective tissue prosthesis, of the present invention. The sheath yarn component, which is preferably braided around the core yarn component, may comprise a plurality of bioabsorbable fibers in turn comprising at least two different chemical compositions.

The deniers of core yarn component 12 and sheath yarn components 14 and 16 are not especially critical and those of commercially available yarns such as Vicryl (a glycolide/lactide copolymer suture available from Ethicon) and Dexon (a polyglycolide suture available from American Cyanamid) are suitably employed.

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Preferably, the deniers are selected so as to provide a composite yarn having an overall denier of from about 40 to about 1200 and preferably from about 80 to about 500, the overall denier of the core and/or sheath yarn components being from about 20 to about 600 and preferably from about 40 to about 300. The deniers of individual filaments in the core and sheath yarn components of multifilamentous construction can vary widely, e.g., from about 0.2 to about 6.0 and preferably from about 0.4 to about 3.0. The base weight for a desired composite yarn will determine the size and weight of the component elements of the yarn. Composite yarn 10 possesses sufficient core material to impart, inter alia, a desired resiliency and sufficient sheath material to provide, inter alia, a desired tensile strength for a particular connective tissue prosthetic application. In general, the core component can represent from about 20 to about 80 percent, and preferably from about 30 to about 70 percent of the total weight of composite yarn 10. Optimum core and sheath component weights will naturally vary depending on the specific application and can be readily determined in a given case based on the desired physical properties of the prosthetic device without undue experimentation.

Methods and apparatus for covering core yarn components with sheath yarn components are well known and need not be described here in detail. In general, the sheath yarn components are wrapped about the core yarn component on a covering machine which includes a hollow spindle with rotating yarn supply bobbins supported thereon. The elastic core yarn component is fed through the hollow spindle and the elastic sheath yarn components are withdrawn from the alternate direction rotating supply bobbins and wrapped about the core yarn component as it emerges from the hollow spindle. The core yarn component is preferably under a slight tension during the covering procedure and the sheath yarn components are laid down in a side-by-side array. The number of wraps per inch will depend on the denier of the sheath yarn components but should be sufficient to cause the sheath yarn components to lay close to the core yarn component when tension on the latter is relaxed.

As desired, the filaments which comprise a sheath yarn component can be provided with no twist or with varying degrees of twist. Where the yarns are twisted, it can be advantageous to balance or equalize the twist in the final composite yarn structure. Thus, for example, in the embodiment of composite yarn 10 in FIG. 1, if sheath yarn component 14 has a given twist, sheath yarn component 16 should have an equivalent twist. Since sheath yarn components 14 and 16 are laid down in opposite directions, the twist in each of these yarn components will be neutralized in the final structure of the composite yarn. Similarly, sheath yarn components 14 and 16 are advantageously of about equal weight in order to provide further balance in the composite yarn.

The composite yarn 20 shown in FIG. 2 is similar to that of FIG. 1 except that core yarn component 22 constitutes a monofilament and internal and external sheath yarn components 24 and 26, respectively, each constitutes a monofilament. In all other structural and compositional respects, composite yarn 20 can be like that of composite yarn 10.

An alternative composite yarn 30 is illustrated in FIGS. 3 and 4. Composite yarn 30 comprises a core yarn component 33 and a braided sheath yarn component 34. As with core yarn components 12 and 22 of

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FIGS. 1 and 2, core yarn component 33 is made up of one or more biocompatible, essentially non-bioabsorbable and preferably elastic filaments 36 which define the longitudinal axis of composite yarn 30. Braided sheath yarn component 34 comprises individual sheath yarn filaments or sheath yarn filament bundles 35 which traverse core yarn component 33 in a substantially conventional braided configuration to provide core yarn component 33 with a braided tubular external sheath 34. The individual sheath yarn filaments or sheath yarn filament bundles 35 are biocompatible, bioabsorbable or semi-bioabsorbable, and relatively inelastic. In a preferred embodiment of the present invention as illustrated in FIGS. 3 and 4, sheath yarn component 34 comprises sheath yarn filaments of different chemical composition. For example, a portion of the sheath yarn filaments 35, e.g., 30 to 70% by weight, may be formed of a bioabsorbable polymer exhibiting relatively slow bioabsorption, e.g., polylactide or a copolymer comprising a high lactide mole percentage, while the remainder of the sheath yarn filaments 35 may be formed of a second bioabsorbable polymer which exhibits relatively fast bioabsorption, e.g., polyglycolide or a copolymer comprising a high glycolide mole percentage. Sheath yarn component 34 may also be fabricated from individual filaments having more than two different chemical compositions, one or more of which optionally being nonbioabsorbable.

In the embodiment illustrated in FIGS. 3 and 4, core yarn component 33 is preferably manufactured from Hytrel filaments 36 and has a denier of about 270, while sheath yarn component 34, which is braided on an eight carrier braider, has a denier of about 204, for a total denier of this composite yarn 30 of about 474.

FIG. 5 illustrates an anterior cruciate ligament prosthesis 37 manufactured from warp and filling composite yarns 10 of FIG. 1. Prosthesis 37 is constructed by constructing a sheath 31 about core 32 by weaving, braiding or knitting on a known or conventional loom. For example, the sheath may be braided about the core on a braiding machine which includes braider bobbins. Composite yarn forming the sheath may be wound onto an appropriate number of braider bobbins which are then loaded onto a carrier braider with the yarns on the bobbins then being braided and tied to form the sheath. The core (if one is required) can be pulled through the sheath, e.g. manually to form the prosthesis. In other words, the core will be at least partially surrounded by the sheath. Other prostheses illustrated herein can be manufactured in similar fashion. The sheath components of the individual composite yarns from which ligament prosthesis 30 is manufactured will erode over time due to their bioabsorption leaving only the nonabsorbable core component as a permanent or long term scaffold for new ligament tissue growth.

FIGS. 7-11 illustrate examples of other ligament prostheses which can be manufactured from the composite yarn of the present invention, e.g. as illustrated in FIGS. 1-3. More particularly, FIG. 7 illustrates a tubular ligament prosthesis or tendon augmentation device 40 having an unbraided center section 41 bounded by braided sections 42 and 43. The individual composite yarns 44 in the unbraided center section 41 can be drawn in generally parallel relationship, if required. The length of the unbraided center section 41 can vary, e.g., from about one or two inches up to about seven or eight inches. The unbraided center section 41 provides tensile strength and/or tissue ingrowth advantages.

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Additionally, a tubular ligament prosthesis or tendon augmentation device 45 as illustrated in FIG. 8 can be manufactured from the composite yarn of the present invention. The prosthesis 45 is similar to the one illustrated in FIG. 7 and comprises an unbraided center section 46 bounded by braided sections 47 and 48. A helical wrap 100 is provided about the unbraided center section 46 to improve handling and manipulation of the unbraided section 46 during implantation, while absorption/degradation of the helical wrap 100 frees the individual yarns 49 of the center unbraided section 46 to provide the appropriate tensile strength and/or tissue ingrowth advantages. In this regard, the yarn forming the helical wrap 100 can be the composite yarn of FIGS. 1-3 or formed of a different kind of material, e.g. completely bioabsorbable or nonbioabsorbable material. The tubular ligament prostheses of FIGS. 7 and 8 are both constructed by braiding the end sections 42, 43 or 47, 48 in a known or conventional loom and, in the case of FIG. 8, additionally wrapping the helical yarn 100 about the center unbraided section 46, also with a known or conventional loom. The prostheses of FIGS. 7 and 8 are especially suitable as replacements for anterior cruciate ligaments.

FIG. 9 illustrates a braided prosthesis 70 which can be manufactured from the composite yarns of FIGS. 1-3 and which is also modified along the length thereof. More specifically, the prosthesis of FIG. 9 comprises a center region 50 bordered by first outer regions 51, 52, second outer regions 53, 54, third outer regions 55, 56, fourth outer regions 57, 58, and fifth outer regions 59, 60. The center region 50 comprises a sheath of braided composite yarn, e.g., as illustrated in FIGS. 1-3, about a core (not illustrated) also formed of composite yarn. First outer regions 51, 52 additionally comprise a wrapping 61 about the braided yarn, this wrapping 61 being formed of the same composite yarn as illustrated in FIGS. 1-3 or a different kind of material, e.g. a totally bioabsorbable or nonabsorbable material. This wrapping 61 serves to at least temporarily retain the sheath about the core.

The second outer regions 53, 54 also formed of tubular braided composite yarn as illustrated in FIGS. 1-3 with an appropriate core material (not illustrated) that forms a thicker core than any core present in center section 50 (the center section 50 can be coreless, if required). Third outer regions 55, 56 are divided as illustrated in FIG. 9 to form respective openings 62 and 63. This allows attachment means to be inserted through the respective openings to secure the ligament prosthesis 70 in place. As illustrated in FIG. 9, the sections 55, 56 around the openings 62 and 63 are also covered with wrapping 64 which is similar to the wrapping 61 covering regions 51 and 52.

Next, fourth outer regions 57 and 58 follow which are similar in structure and composition to second outer regions 53 and 54. Regions 57 and 58 narrow down into fifth outer regions 59 and 60 as illustrated in FIG. 9, which can be used, e.g. for threading the ligament prosthesis 70. All sections of prosthesis 70, including the various wrappings 61 and 64, can be fabricated together on a conventional known loom. Prosthesis 70 is especially suitable as a replacement for an anterior cruciate ligament.

FIG. 10 discloses a coreless prosthetic ligament 80 that can be prepared from the composite yarn illustrated in FIGS. 1-3. The coreless prosthetic ligament is braided with a wider central section 81, and a narrower

outer section from which unwoven yarns 83 extend to form a leading section to enhance threading of prosthetic ligament 80 upon implantation. Sheath yarns 84 of prosthetic ligament 80 can be woven, braided, or knitted on a conventional loom. Sheath sections 81 and 82 of ligament prostheses 80 are tubular, i.e. coreless. Prostheses 80 is also especially suitable as a replacement for an anterior cruciate ligament.

As illustrated in FIG. 11, a ligament prosthesis 90 can be prepared from composite yarns illustrated in Figs. 1-3 of the present invention which form a sheath about a supporting structure (not illustrated). This supporting structure can be a core formed from the composite yarns as described above, or it can be a single, integral member, formed of semi-bioabsorbable or non-bioabsorbable material forming a supporting base for yarns 91. This supporting structure, along with the bundle of yarns 91, can be divided into two branches 90a and 90b, with the yarns 91 of the prosthesis retained on the supporting structure or core at various points by fastening means 92 which can also be constituted by composite yarn of FIGS. 1-3 or by other kinds of material, e.g. totally bioabsorbable or nonabsorbable filaments. In this regard, the yarns 91 need just be bundled together without any interweaving, braiding or knitting, so long as the yarns 91 are securely held together on the core by the fastening means 92. Alternatively, yarns 92 can be woven, knitted, or braided about the core on a conventional loom to form branches 90a and 90b.

Other prosthetic structures which can be prepared with the composite yarn of the present invention are apparent to one of skill in the art in light of the disclosure herein.

It is within the scope of this invention to coat or impregnate the prosthesis with, or otherwise apply thereto, one or more materials which enhance its functionality, e.g., surgically useful substances, such as those which accelerate or beneficially modify the healing process when the prosthesis is applied to a graft site. So, for example, the prosthesis can be provided with a therapeutic agent which will be deposited at the grafted site. The therapeutic agent can be chosen for its antimicrobial properties, capability for promoting tissue repair or for specific indications such as thrombosis. Thus, for example, antimicrobial agents such as broad spectrum antibiotics (gentamicin sulphate, erythromycin or derivatized glycopeptides) which are slowly released into the tissue can be incorporated into the prosthesis to aid in combating clinical and sub-clinical infections in a surgical or trauma wound site.

To promote wound repair and/or tissue growth, one or several growth promoting factors can be introduced into the tubular prosthesis, e.g., fibroblast growth factor, platelet derived growth factor, macrophage derived growth factor, alveolar derived growth factor, monocyte derived growth factor, magainin, and so forth. To decrease abrasion, increase lubricity, etc., the prosthesis can be coated with copolymers of glycolide and lactide and polyethylene oxide, calcium salts such as calcium stearate, compounds of the Pluronic class, copolymers of caprolactone, caprolactone with PEO, polyHEMA, etc. Especially advantageous is a coating of hyaluronic acid with or without cross-linking.

Additionally, polypeptides such as Human Growth Factor (HGF) can also be coated upon or impregnated in the prosthesis to promote healing. The term "Human Growth Factor" or "HGF" embraces those materials, known in the literature, which are referred to as such

and includes their biologically active, closely related derivatives. The HGFs can be derived from naturally occurring sources and are preferably produced by recombinant DNA techniques. Specifically, any of the HGFs which are mitogenically active and as such effective in stimulating, accelerating, potentiating or otherwise enhancing the wound healing process are useful herein, e.g., hEGF (urogastrone), TGF-beta, IGF, PDGF, FGF, etc. These and other useful HGFs and closely related HGF derivatives, methods by which they can be obtained and methods and compositions featuring the use of HGFs to enhance wound healing are variously disclosed, inter alia, in U.S. Pat. Nos. 3,883,497; 3,917,824; 3,948,875; 4,338,397; 4,418,691; 4,528,186; 4,621,052; 4,743,679 and 4,717,717; European Patent Applications 0 046 039; 0 128 733; 0 131 868; 0 136 490; 0 147 178; 0 150 572; 0 177 915 and 0 267 015; PCT International Applications WO 83/04030; WO 85/00369; WO 85/01284 and WO 86/02271 and UK Patent Applications GB 2 092 155 A; 2,162,851 A and GB 2 172 890 A, all of which are incorporated by reference herein. Of the known HGFs, hEGF, TGF-beta and IGF are preferred for use in the therapeutic composition of this invention.

The HGFs can be introduced with appropriate carrier such as carrier proteins disclosed, e.g., in "Carrier Protein-Based Delivery of Protein Pharmaceuticals", a paper of Biogrowth, Inc., Richmond, Calif., presented at a symposium held June 12-14, 1989 in Boston, Mass.

EXAMPLE 1

The following illustrates the manufacture of a ligament prosthesis as illustrated in FIG. 5.

A 420 denier composite yarn as illustrated in FIG. 1 was formed from a Hytrel 7246 yarn as the core component and a lactide (80 mole percent)-glycolide (20 mole percent) copolymer yarn providing the sheath component.

Six plies of the 420 denier composite yarn were wound onto 32 braider bobbins. The bobbins were loaded onto a 32 carrier braider to provide braided sheath 31. About one meter of the yarns from the 32 bobbins was pulled manually in parallel to provide a core 32 of 80,640 (420 x 6 x 32) overall denier. Application of braided sheath 31 also 420 x 6 x 32 or 80,640 overall denier resulted in ligament prosthesis 37 possessing an overall denier of 161,280. The stress (force in Newtons)-strain characteristics of prosthesis 37 were measured and compared with the stress-strain characteristics of a human anterior cruciate ligament as reported in Noyes et al., *Journal of Bone and Joint Surgery*, Vol. 58-A, No. 8, p. 1074, et seq. (Dec. 1976). As shown in the plotted data of FIG. 6, the stress-strain characteristics of prosthesis 37 (continuous line) closely matched those of the natural tissue (broken line), an altogether remarkable achievement relative to known connective tissue prostheses.

EXAMPLE 2

The following illustrates manufacture of a tendon augmentation device 40 as illustrated in FIG. 7.

A 431 denier composite yarn as illustrated in FIG. 1 was formed from a Hytrel 7246 yarn to provide the core component 12, a lactide (80 mole percent)-glycolide (20 mole percent) copolymer yarn to provide the inner sheath component 14, and a lactide (10 mole percent)-glycolide (90 mole percent) copolymer yarn to provide the outer sheath component 16.

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Six plies of the 431 denier composite yarn were wound onto 16 braider bobbins. The bobbins were loaded onto a 16 carrier braider to provide braided sections 42 and 43. About 70 mm of the yarn from the 16 braider bobbins was braided to form one of sections 42 and 43, and then the braiding was stopped. Then, about 35 mm. of the yarn from the 16 braider bobbins was pulled manually to form the unbraided center section 41, and then braiding was continued for another 70 mm of the yarn to form the other of sections 42 and 43. The resulting tendon augmentation device 40 had a total denier of 41,376 (431×6×16).

The tendon augmentation device 40 was implanted in a canine knee replacing the center third of the patellar tendon. Physical testing was carried out comparing two tendon augmentation devices 40 (TAD-1 and TAD-2) to the center third of the canine patellar tendon (P.T.) being replaced. More specifically, the stress (force in Newtons) —strain or load-deformation characteristics of devices 40 and the canine patellar tendon were measured and compared with one another.

As shown in the plotted data of FIG. 12, the responses of both tendon augmentation devices 40 (TAD 1 and TAD 2) were very similar to the one third canine patellar tendon. Moreover, tendon augmentation devices 40 (TAD 1 and TAD 2) were generally stronger than the replaced canine patellar tendon which failed when too great a load was applied thereto.

EXAMPLE 3

A composite yarn as illustrated in FIGS. 3 and 4 was fabricated using Hytrel 7246 fibers as the core component 33 and bioabsorbable sheath component fibers 35 of two different chemical compositions: first bioabsorbable fibers 35' fabricated from an 80 mole percent lactide/20 mole percent glycolide copolymer, and second bioabsorbable fibers 35'' fabricated from a 10 mole percent lactide/90 mole percent glycolide copolymer. The first bioabsorbable fibers 35' were formed into yarn bundles, each yarn bundle comprising 12 filaments and having a total denier of 24. The second bioabsorbable fibers 35'' were also formed into yarn bundles, each yarn bundle comprising 17 filaments and having a total denier of 27.

The composite yarn was formed using three Hytrel yarn bundles, each Hytrel yarn bundle comprising 70 filaments, to form a core component 33 of approximately 270 denier. The braided sheath component 34 was formed around the Hytrel core component 33 using an 8 carrier braider, 4 carriers each of the first and second bioabsorbable yarn bundles. The composite yarn thus formed exhibited a tensile strength of 3.19 grams/denier, and is suitable for use in fabricating a connective tissue prosthesis of the present invention.

What is claimed is:

1. A connective tissue prosthesis comprising:
a) a core made up of a first biocompatible composite yarn extending in a lengthwise direction; and
b) a sheath surrounding the core, said sheath being fabricated from a second biocompatible yarn;
the first composite yarn in said core (a) comprising a non-bioabsorbable core yarn component surrounded by an at least semi-bioabsorbable sheath yarn component.

2. The connective tissue prosthesis of claim 1, wherein the second biocompatible yarn in said sheath (b) comprises a non-bioabsorbable core yarn component

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surrounded by an at least semi-bioabsorbable sheath yarn component.

3. The connective tissue prosthesis of claim 2 wherein the sheath yarn component is bioabsorbable.

4. The connective tissue prosthesis of claim 1 exhibiting stress-strain characteristics approximately those of the natural connective tissue replaced or augmented by the prosthesis.

5. The connective tissue prosthesis of claim 1 wherein said connective tissue prosthesis is a ligament or tendon prosthesis.

6. The connective tissue prosthesis of claim 1 wherein said connective tissue prosthesis is a human anterior cruciate ligament prosthesis.

7. The connective tissue prosthesis of claim 1 in which the core component comprises at least one filament.

8. The connective tissue prosthesis of claim 7 in which the core (a) of the prosthesis comprises multiple composite yarns.

9. The connective tissue prosthesis of claim 7 wherein the core component comprises multiple filaments.

10. The connective tissue prosthesis of claim 1 in which the sheath component comprises at least one filament.

11. The connective tissue prosthesis of claim 10 wherein the sheath yarn component comprises multiple filaments.

12. The connective tissue prosthesis of claim 1 in which the core component is manufactured from at least one polymeric material selected from the group consisting of polyethylene homopolymers, polypropylene homopolymers, ethylene-propylene copolymers, ethylene propylene terpolymers, fluorinated hydrocarbons, fluorosilicones, isobutylenes, isoprenes, polyacrylates, polybutadienes, polyurethanes, and polyether-polyester copolymers.

13. The connective tissue prosthesis of claim 1 in which the core component possesses an elongation at break of at least about 30 percent.

14. The connective tissue prosthesis of claim 1 in which the sheath component is an absorbable, relatively inelastic polymeric material derived at least in part from a monomer selected from the group consisting of glycolic acid, glycolide, lactic acid, lactide, p-dioxanone, trimethylene carbonate, ε-caprolactone and hydroxyacetic acid.

15. The connective tissue prosthesis of claim 1 in which the sheath component is a lactide-glycolide copolymer.

16. The connective tissue prosthesis of claim 12 in which the sheath component is a lactide-glycolide copolymer containing from about 70 to about 90 mole percent lactide units.

17. The connective tissue prosthesis of claim 16 in which the sheath component is a lactide-glycolide copolymer containing from about 75 to about 85 mole percent lactide units.

18. The connective tissue prosthesis of claim 1 wherein the sheath (b) covering the core (a) is at least partially woven.

19. The connective tissue prosthesis of claim 18 wherein the sheath (b) is entirely woven.

20. The connective tissue prosthesis of claim 1 further comprising at least one bioactive substance.

21. The connective tissue prosthesis of claim 1, wherein said sheath component is helically wound about said core component.

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22. The connective tissue prosthesis of claim 21, additionally comprising

a second sheath component helically wound about said sheath component in a different direction.

23. The connective tissue prosthesis of claim 22, in which said second sheath component is a lactide-glycolide copolymer.

24. The connective tissue prosthesis of claim 22, wherein said first and second sheath components have different ratios of absorption.

25. The connective tissue prosthesis of claim 1, wherein said sheath component is braided around said core component.

26. The connective tissue prosthesis of claim 25, wherein said sheath component comprises a plurality of bioabsorbable fibers, said fibers comprising at least two different chemical compositions.

27. The connective tissue prosthesis of claim 1, wherein said core (a) and sheath (b) together are branched at discrete locations to form gaps between branches of said prosthesis.

28. The connective tissue prosthesis of claim 27, wherein a yarn is wrapped about said sheath (b) at discrete locations to at least temporarily retain said sheath (b) about said core (a).

29. The connective tissue prosthesis of claim 28, wherein said wrapping yarn comprises a biocompatible, non-bioabsorbable core yarn component surrounded by a at least semi-bioabsorbable sheath yarn component.

30. The connective tissue prosthesis of claim 29 wherein said sheath component of said wrapping yarn is bioabsorbable.

31. The connective tissue prosthesis of claim 1 wherein said sheath yarn component is bioabsorbable.

32. The connective tissue prosthesis of claim 1 wherein the sheath (b) covering the core (a) is at least partially braided.

33. The connective tissue prosthesis of claim 32 wherein the sheath (b) is entirely braided.

34. The connective tissue prosthesis of claim 1 wherein the sheath (b) covering the core (a) is at least partially knitted.

35. The connective tissue prosthesis of claim 34 wherein the sheath (b) is entirely knitted.

36. A connective tissue prosthesis comprising:
a tubular component fabricated from composite yarn, said yarn comprising a biocompatible, core yarn component surrounded by a biocompatible, at least semi-bioabsorbable sheath yarn component.

37. The connective tissue prosthesis of claim 36, comprising a center section where said yarn is unbraided and bordered by sections where said yarn is braided.

38. The connective tissue prosthesis of claim 37, additionally comprising

a helical wrap about said unbraided center section.

39. The connective tissue prosthesis of claim 38, wherein said helical wrap is fabricated from composite yarn comprising a biocompatible, non-bioabsorbable

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core yarn component surrounded by a biocompatible, at least semi-absorbable sheath yarn component.

40. The connective tissue prosthesis of claim 39, wherein said sheath component is bioabsorbable.

41. The connective tissue prosthesis of claim 36, additionally comprising

a threading member attached to an end thereof, said threading member comprising a composite yarn which comprises a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, at least semi-bioabsorbable sheath yarn component.

42. The connective tissue prosthesis of claim 41 wherein said sheath component is bioabsorbable.

43. The connective tissue prosthesis of claim 36 wherein said sheath component is bioabsorbable.

44. Method for manufacturing a connective tissue prosthesis, comprising

forming said connective tissue prosthesis from a first biocompatible composite yarn comprising a non-bioabsorbable core yarn component surrounded by an at least semibioabsorbable sheath yarn component.

45. The method of claim 44, wherein said connective tissue prosthesis comprises a core and a sheath, said core being at least partially surrounded by said sheath.

46. The method of claim 45, wherein said biocompatible composite yarn forms said core.

47. The method of claim 44, wherein said biocompatible composite yarn forms said sheath.

48. The method of claim 44, wherein the sheath is woven about the core.

49. The method of claim 48, wherein the sheath is braided from braider bobbins loaded onto a carrier braider, and the core is pulled through the thus-braided sheath.

50. The method of claim 48 wherein the sheath is braided about the core.

51. The method of claim 44 wherein said sheath component is bioabsorbable.

52. The method of claim 44 wherein the sheath is knitted about the core.

53. Method for manufacturing a tubular connective tissue prosthesis, comprising

forming a tubular component from composite yarn comprising a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, at least semi-absorbable sheath yarn component.

54. The method of claim 53 wherein the tubular component is formed by weaving.

55. The method of claim 53 wherein the tubular component is formed by braiding.

56. The method of claim 55, wherein the tubular component is braided from braider bobbins loaded onto a carrier braider.

57. The method of claim 53 wherein the tubular component is formed by knitting.

58. The method of claim 53 wherein the sheath component is bioabsorbable.

* * * * *

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Pinchuk et al.

[45] Date of Patent: May 26, 1992

[54] MESH COMPOSITE GRAFT

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[22] Filed: Dec. 27, 1990

[51] Int. Cl.³ A61F 2/06

[52] U.S. Cl. 623/1; 623/11;

[58] Field of Search 623/12, 1

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Primary Examiner—David Isabella
Assistant Examiner—Debra S. Brittingham

19 Claims, 1 Drawing Sheet

[57] ABSTRACT

A mesh composite graft including an inner component, an outer component formed from strands of durable material, such as polyethylene terephthalate, and an intermediate component made from strands of biocompatible synthetic material having a melting point less than that of the durable material from which the outer component is formed and less than that of the biocompatible synthetic material from which the inner component of the graft is formed. By heating the graft to a temperature greater than the melting point of the material from which the intermediate component is formed but less than the melting point of the outer component material and less than the melting point of the material from which the inner component is formed, the components are bound by the melted intermediate component to provide a totally porous, compliant composite graft reinforced by the outer component.

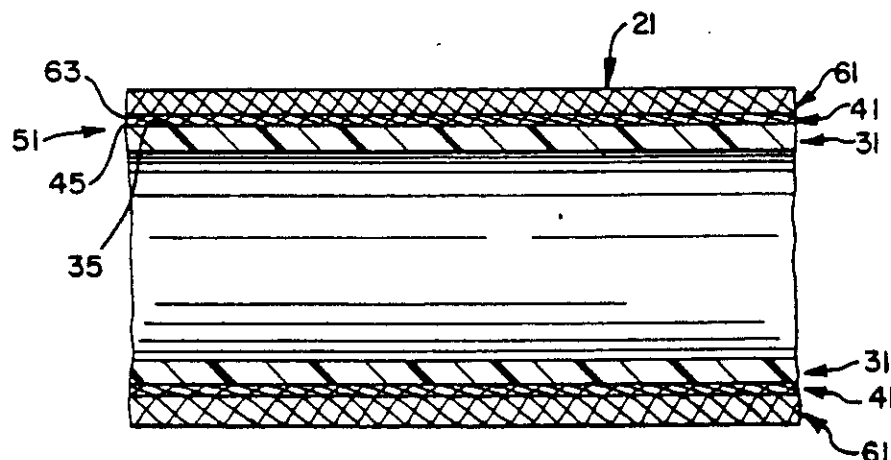


FIG. 1

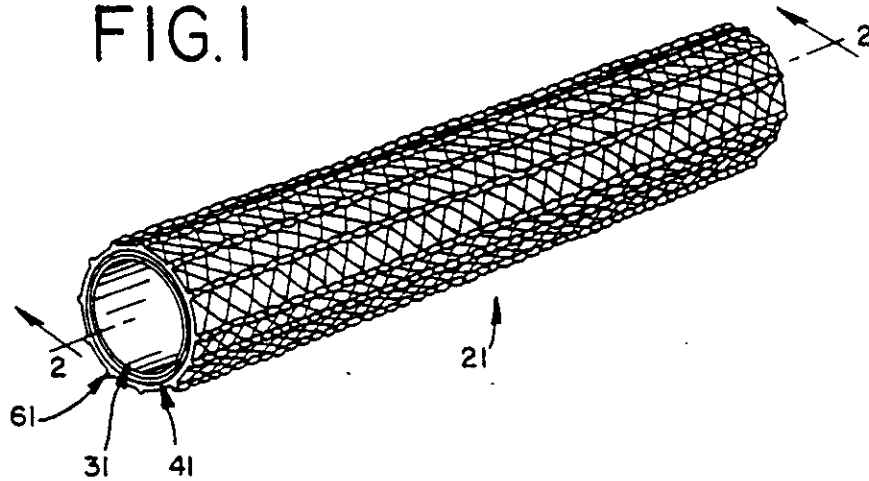
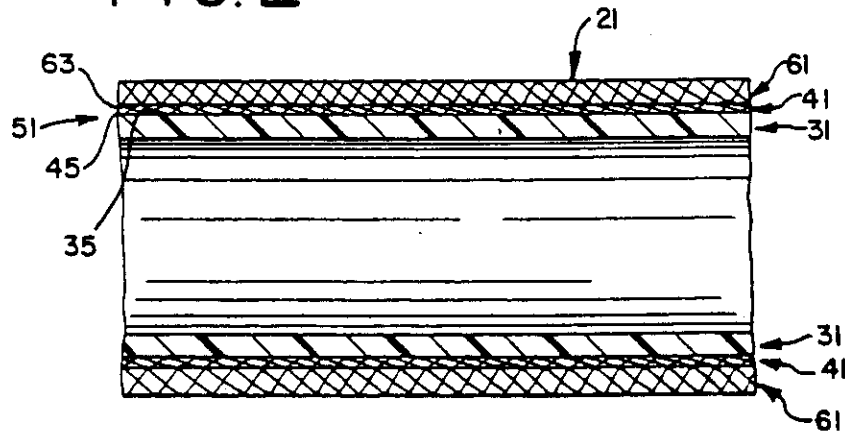


FIG. 2



MESH COMPOSITE GRAFT

BACKGROUND AND DESCRIPTION OF THE INVENTION

The present invention generally relates to implantable prostheses and the like and to methods for making same. More particularly, the invention relates to a graft, such as a vascular graft or AV-shunt, having a compliant porous inner component and a compliant porous load-bearing outer component, bound together by a porous intermediate component that is made of material having a melting point lower than that of the materials from which the inner and outer components are made. With the outer component bound by the intermediate component to the inner component, a porous, yet strengthened integral graft results.

Blood vessels are not straight, rigid tubes but elastic conduits made of a variety of materials and having a compliance that varies with functional considerations. For example, the venous system functions, in part, as the blood reservoir for the body. In order to be able to respond to a larger volume of blood sent into the system because of, for example, a change in arterial blood pressure, the vessels of the venous system must be sufficiently compliant so that they can distend. The arterial system functions as the body's pressure reservoir. In order to avoid the wide swings in the blood pressure and flow that are possible with every contraction and relaxation of the heart, yet be able to maintain sufficient blood pressure so that blood can be pushed into all regions of the body, including through the small-diameter arterioles and the microcirculatory bed, the arteries must have sufficient compliant strength to elastically expand and recoil without the marked distension of the venous system.

Conventional grafts, however, are generally made of materials and in shapes that provide a structure whose compliance is markedly different from that of the walls of the vessel to which they may be attached. Grafts having walls less compliant than that of the host vessel walls are problematic in that conditions, such as intimal hyperplasia and stenotic narrowing, may develop. Grafts with walls having greater compliance than that of the vessel to which the graft is attached are problematic in that a portion of the graft wall may balloon—that is, develop an aneurysm—after implantation.

Other known grafts, while they may be compliant, may not necessarily be made from biocompatible materials. The implantation of a graft made from such material may prompt a thrombogenic or immunological response with the resultant deleterious formation of microthrombi or microocclusions in and around the graft. Other grafts are made from generally non-porous materials, that, accordingly, do not facilitate the ingrowth of cells and tissue within the graft. The full incorporation of the graft into the surrounding host tissue is thereby frustrated. Still other conventional grafts are made from microporous textiles that require preclotting of the vessel wall with blood to prevent leakage of blood at implantation.

A demand therefore is present for an integral graft made from biocompatible materials and having a structure that has compliant strength similar to that of natural tissue but that is sufficiently porous so that the graft may become incorporated into the host tissue yet not leak blood. The present invention satisfies the demand.

The present invention includes a three component system, an inner component, an intermediate component, and an outer component. While the components may be made from materials having generally different melting points and different mechanical properties, at a minimum the inner component and outer component are made from a material or materials having a melting temperature higher than the material from which the intermediate component is made. More specifically, the inner component is porous and is made from a biocompatible synthetic material, preferably a polyurethane composition made with an aromatic polycarbonate intermediate, having a melting point that is, at a minimum, in excess of the melting point of the composition from which the intermediate component is formed (further discussed below).

There are many methods by which the inner component may be made, such as the many known methods used to produce porous compliant vascular prostheses. One such method is termed phase inversion or separation which involves dissolving a urethane in a solvent, such as dimethyl acetamide (DMA), forming a coat on a mandrel—such as by dipping the mandrel into the dissolved urethane—and then immersing the urethane coating in a solution such as water by which DMA may be dissolved, but not urethane, thereby causing the urethane to bead-up and form a porous matrix.

Another method by which the inner component may be formed is termed particle elution. The method utilizes water soluble particles such as salt (NaCl, MgCl₂, CaCO₂, etc.) polymers, such as polyvinylpyrrolidone, sugars etc. The particles are mixed or blended into a urethane composition, and after forming a graft from the mixture such as by dip coating or extruding the particle filled plastic, the particle is eluted out with a suitable solvent.

Additional methods include replamineform, that involves the dissolution of a matrix, such as that of a sea urchin, out of the urethane with hydrochloric acid, spray techniques where filaments or beads of urethane are sprayed onto a mandrel to produce a porous vascular graft, and electrostatic deposition of urethane fibers from solution.

However, the porous vascular graft preferred in this invention is prepared according to the method detailed in U.S. Pat. No. 4,475,972 to Wong. This patent is incorporated herein by reference. An antioxidant may be added to further prevent degradation of the fibers drawn of the material from which the inner component is made.

Regardless of the nature and method of manufacturing the porous inner component, the intermediate component is comprised of one or more layers of a biocompatible synthetic material, preferably a polyurethane material, having a melting point lower than the melting point of the material from which the inner component is formed and lower than the melting point of the material from which the outer component is made.

The outer component comprises a mesh network made of strands, fibers, beads or expanded versions of a durable material such as a composition of fluorocarbons, such as expanded polytetrafluoroethylene ("ePTFE")—commonly termed Teflon—or stable polyesters, such as preferably polyethylene terephthalate ("PET")—commonly termed Dacron. This material is preferably warp-knitted in a tricot or double tricot pattern and shaped in a tubular configuration. It can also be appreciated that the outer component can be woven, braided,

weft-knitted and the like with loose fibers, textured fibers and the like to provide increased compliance. With the three components in place, a composite graft according to the present invention is formed by heating the structure to a temperature at or above the melting point of the material from which the intermediate component is formed but below the melting temperature or temperatures of the material from which the outer component is formed and of the material from which the inner component is formed. In this temperature range, the intermediate component may melt without the melting of either the inner component and the outer component, thereby mechanically bonding the inner component to the outer component.

The multi-component system of the present invention provides a number of advantages over conventional grafts. The use of a durable material, such as PET or ePTFE, from which the outer component may be formed is advantageous because of the known strength that such material has in the body. Devices made from PET or ePTFE when implanted in the body are known to maintain their integrity for some three decades. Further advantageously, it has been found that a graft—made according to the present invention and in which PET is used to form the outer component—has a burst strength and a tensile strength that is some two times greater than that of a conventional graft. Such strength prevents the dilation of the vessel in response to, for example, an increase in blood flow and/or pressure, creep relaxation of the urethane, biodegradation of the urethane, plasticization of the urethane, etc. Decreases in the strength of PET that may occur after implantation due, for example, to the absorption of water after implantation, are minimal as Dacron has a low water absorption ability.

The use of a knitted pattern according to which the durable strands of the outer component may be configured is advantageous due to the increased compliance such a pattern provides. As stated above, a durable material such as PET is recognized as a strong yet not necessarily compliant material. However, by knitting the strands from which the outer component is formed into a network, a compliant reinforcing outer component is formed. The use of such a material from which to form the outer component in the three component system of the present invention advantageously provides a strengthened, yet compliant graft.

The winding of strands of synthetic material, such as polyurethane over a mandrel to form an inner component is further advantageous because of the resultant porosity of the component. While the intermediate component may be made porous, for example, by painting synthetic material over the inner component and utilizing the phase inversion method or the particle elution method to form a porous matrix, preferably the intermediate component is formed by winding strands of synthetic material, such as polyurethane over the inner component, to provide a highly porous network. Utilizing strands of PET configured in a knitted pattern to form the outer reinforcement component further provides a porous network. Advantageously, by combining these individually porous components together in a composite graft, a totally porous integral graft results. Porosity is an advantage in medical devices, such as vascular grafts, because an open structure allows vascular fluid to infiltrate and communicate to and from the surrounding tissue and the interior of the graft and allows the ingrowth of tissue to occur within the

graft. Accordingly, the device becomes better incorporated into the surrounding tissue, thereby further securing the device within the implantation site.

Uniting the three components into a single composite graft advantageously facilitates the use of the device. The graft may be implanted without the need for any assembly immediately prior to use. The graft may be also cut and/or sutured as a unit without the need for the separate cutting and/or suturing of each component. Methods for cutting the composite graft include scalpel, scissors, hot wires, shaped blades, and the like. The speed with which the graft may be implanted is a particularly distinct advantage since the device is implanted only when a patient is undergoing surgery.

The use of a polycarbonate intermediate rather than, for example, a polyether urethane to make the polyurethane material from which the inner component is preferably made is advantageous as the resultant inner component better resists degradation. The resistance to degradation is further aided by the addition of antioxidant to the material from which the inner component is formed.

It is, accordingly, a general object of the present invention to provide an improved graft.

Another object of the present invention is to provide an integral improved graft made from a composite of layers of synthetic materials.

It is also an object of the present invention to provide a graft that is totally porous thereby facilitating the incorporation of the graft into the site of implantation.

An additional object of the present invention is to provide an improved graft having an outer component which strengthens the device without significantly impairing the overall compliance of the graft.

These and other objects, features and advantages of this invention will be clearly understood and explained with reference to the accompanying drawings and through a consideration of the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

In the course of this description, reference will be made to the attached drawings, wherein:

FIG. 1 is a perspective view illustrating an embodiment of a composite vascular graft according to the present invention with an outer component of knitted durable material positioned over and bound by an intermediate component to an inner component; and

FIG. 2 is a cross sectional view of the composite vascular graft according to the present invention illustrated in FIG. 1.

DESCRIPTION OF THE PARTICULAR EMBODIMENTS

The present invention is a composite vascular graft—generally designated as 21 in FIGS. 1 and 2—comprised of an inner component 31, an intermediate component 41, and an outer component 61. The inner component will be described first.

Inner component 31 is fabricated from a biocompatible synthetic material, preferably polyurethane, having a melting temperature that is, at a minimum, greater than the melting temperature of the material from which the intermediate component is formed. Preferably, in those embodiments in which the inner component 31 is formed from polyurethane, it is made with an aromatic polycarbonate urethane. Polycarbonate urethanes are preferred over polyether urethanes due to

their superior biostability. The aromatic polycarbonate urethanes have melting points in the range of 150° C. to 230° C. This is in contrast to some aliphatic polycarbonate urethanes that have melting points between 90° C. and 130° C. It can also be appreciated that the inner member may be composed of non-urethane materials such as silicone rubber, polyolefins, fluoroelastomers, ePTFE, and the like. An antioxidant, such as Irganox 1010, may be added to the inner member to further prevent degradation of the strands from which the inner component is formed. The melting temperature of the material from which the inner component is preferably formed exceeds 150° C.

The methods by which the inner component 31 may be fabricated include those disclosed in U.S. Pat. No. 4,475,972 to Wong. According to a fabrication method taught in the Wong patent, termed "solution processing", the inner component material is dissolved in a solvent and forced out of one or more orifices to form one or more continuous fibers. The fibers are drawn directly onto a rotating mandrel. As the distributor or spinnerette reciprocates along the mandrel, non-woven strands are layered on top of each other to form porous, non-woven network of criss-crossing strands.

The intermediate layer 41 is formed of a biocompatible synthetic material, such as a polyolefin, a silicone thermoplastic material, etc., or preferably a polyurethane material having a melting temperature less than that of the materials from which the inner and outer components are formed. The intermediate layer can be drawn in the manner described in the Wong patent so that at least one fibrous layer is laid over the inner component 31 to form a porous intermediate layer. This intermediate layer can be spun from solution as described in the Wong patent or can be simply wound onto the inner layer from a spool of the biocompatible low melting point material. Alternatively, phase inversion or particle elution methods may be used to form a porous intermediate component. Examples of suitable low melting point biocompatible materials include the aliphatic polycarbonate or polyether urethanes with melting points of 90° C. to 130° C. The resultant porous, non-woven network of strands forming the intermediate component 41, as drawn over the inner component 31 form a unit 51 which facilitates the transmission of fluid.

Mesh 61, composed of strands of durable material, such as PET or ePTFE, knitted or woven in a generally elongated cylindrical shape and whose inner surface 63 is of a diameter equal to or slightly larger than the diameter of the outer surface 45 of the intermediate component 41, is fitted over the intermediate component 41. To provide compliance to the mesh network of strands from which the outer component is formed, the strands are configured preferably in a knitted pattern. Tricot or double tricot warp knit patterns are preferred. Double tricot patterns are further advantageous because they provide greater depth to the outer component 61 and thereby facilitate the acceptance of and retention of sutures and tissue ingrowth through the graft 21. Tricot or double tricot warp patterns are further advantageous in that they are generally more interlocking than other patterns and therefore resist "running". Other acceptable patterns according to which the strands of the outer component 61 may be formed include jersey or double jersey patterns, woven or braided and multiple layers of the above. Also, the

fibers comprising the outer structure may be textured or non-textured and be of a variety of deniers.

The outer component 61 as positioned over the inner component and intermediate component is heated to a temperature equal to or greater than the temperature at which the material from which the intermediate component 41 is formed melts but less than the temperature and/or temperatures at which the material or materials from which the outer component and from which the inner component 31 is formed melts. When the inner component 31 is formed from the preferred material described above, the components are heated to a temperature less than 150° C. but greater than the temperature at which the material from which the intermediate component 41 is formed melts, such as 110° C. By maintaining the three components at such a temperature for a period of time, such as ten minutes, the intermediate component melts thereby securing the outer component 61 and the inner component 31 to each other. To further ensure the secure full engagement of the outer component 61 by the melted intermediate component 41, the outer component 61 may be forcefully pressed into the intermediate component 41 during the heating step such as mechanically and/or with or under pressure. After heating, the united three components are cooled thereby providing an integral mesh composite graft 21.

A mesh composite graft 21 according to the present invention is totally porous and compliant, yet advantageously includes a load bearing component, the outer component 61, which adds strength to the graft and prevents the failure of the graft even in response to greater fluid volume pressures from within, creep relaxation of the inner member and possible biodegradation effects of the inner member.

The advantageous compliance of the composite graft may be adjusted by varying the number of strands from which the inner component and the intermediate component 41 are formed. The compliance of the composite graft 21 may be adjusted also by varying the materials from which the inner component 31 and the intermediate component 41 are formed while maintaining the relationship that the intermediate component 41 must melt at a lower temperature than the materials from which the outer component and the material from which inner component 31 is formed. The compliance of the mesh composite graft 21 may be adjusted further by adjusting the angle at which the strands of the inner component 31 and/or the strands of the outer component 61 are laid down—a higher angle provides a less compliant component and thereby a less compliant graft.

The compliance may be adjusted even further by altering the knitting parameters, such as courses and wales per inch, the stitch density, the fiber denier, the number of strands per filament, the composition of the fibers and filaments such as a mixture of PET and Spandex compositions and whether the outer member is knitted, woven or braided.

The advantageous overall porosity of the graft 21 may be adjusted also in a number of ways. In addition to varying the size and number of the strands from which the inner component 31 and intermediate component 41 are formed, the strands of each component may be drawn at different angles to provide decreased pore size and resultant decreased porosity. Similarly, the porosity of the outer component 61, and thereby the porosity of the composite graft 21 may be varied by varying the

size and/or number of the strands and stitch density used to make the outer component mesh.

It can also be appreciated that the outer component need not be a tube formed specifically for this purpose from materials as above but can also be made from a vascular graft preformed from a porous matrix material such as ePTFE. One such graft is manufactured by W. L. Gore and marketed as a Gore-Tex graft. The ePTFE graft may be sheathed over the previously described inner and intermediate components and heat fused into a similar composite graft described in this document. Similarly, the inner members may be a Gore-Tex graft, the intermediate component, a heat fusible thermoplastic, and the outer component, a Dacron knit.

Regardless of the configuration of the inner, intermediate and outer components of the graft, i.e. be it spun, salt eluted, phase inverted, wound with an outer PET mesh, or in which an ePTFE configuration is utilized, the resultant composite graft 21 as formed may be implanted in vascular locations and retained in place through conventional methods, such as suturing. The preferred use of PET, knitted in a preferred tricot or double tricot pattern, from which to make the outer component 61 of the graft 21 provides a graft having a greater thickness than grafts without such a load bearing component. The outer component 61 facilitates the greater retention of the sutures within the graft.

It will be understood that the embodiments of the present invention as described are illustrative of some of the applications of the principles of the present invention. Modifications may be made by those skilled in the art without departure from the spirit and scope of the invention.

We claim:

1. A composite graft for implantation within a host, comprising:
 - an inner component made from wound, criss-crossing layers of fibers of a first biocompatible synthetic material and shaped to form a porous generally elongated cylindrical shape having a lumen through which blood may flow, said inner component having an outer surface;
 - an intermediate compliant bonding component made from wound, criss-crossing layers of fiber of a second biocompatible synthetic material, said second material having a melting point lower than the melting point of said first material and lower than the melting point of polyethylene terephthalate, said intermediate component positioned generally over and substantially covering said outer surface of said inner component, said intermediate component being porous and having an outer surface;
 - said intermediate component as positioned over said outer surface of the inner component forming a fluid transmission unit;
 - an outer component made from a mesh formed from strands of matrices of durable material, said strands or matrices preformed in a generally elongated cylindrical shape having a lumen therethrough and a diameter which is approximately equal to the outside diameter of said intermediate component, said outer component is positioned over and substantially covering said outer surface of the intermediate component; wherein each said outer component and said inner component is bonded to said intermediate component when each of the compo-

nents is heated to a temperature less than the melting temperature of said first material and said durable material thereby securing said components to each other to form a totally porous mesh composition graft.

2. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said inner component is made is polyurethane.
3. The mesh composite graft according to claim 2, wherein said polyurethane is made with a polycarbonate intermediate.
4. The mesh composite graft according to claim 2, wherein said polyurethane is made with an aromatic polycarbonate urethane.
5. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said inner component is made is silicone rubber.
6. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said inner component is made is a polyolefin.
7. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said inner component is made is a fluoroelastomer.
8. The mesh composite graft according to claim 3, wherein said polyurethane includes an antioxidant to prevent degradation of said inner component.
9. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said intermediate component is made is polyurethane.
10. The mesh composite graft according to claim 9, wherein said polyurethane is an aliphatic polycarbonate.
11. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said intermediate component is made is a polyolefin.
12. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said intermediate component is made is a silicon thermoplastic material.
13. The mesh composite graft according to claim 1, wherein said outer component is further secured to said fluid transmission unit by pressing said outer component into said intermediate component during heating.
14. The mesh composite graft according to claim 1, wherein said mesh is formed by knitting said strands of polyethylene terephthalate.
15. The mesh composite graft according to claim 1, wherein said mesh is formed by knitting said strands of polyethylene terephthalate in a tricot pattern.
16. The mesh composite graft according to claim 1, wherein said mesh is formed by knitting said strands of polyethylene terephthalate in a double tricot pattern.
17. The mesh composite graft according to claim 2, wherein said mesh is formed from strands of expanded polytetrafluoroethylene.
18. The mesh composite graft according to claim 2, wherein said mesh is preformed from strands of polytetrafluoroethylene.
19. The mesh composite graft according to claim 2, wherein said mesh is a preformed porous matrix of expanded polytetrafluoroethylene.



BTH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511

Art Unit: 1504

Filed : February 19, 1992

Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

December 2, 1992

(Date of Deposit)

Matthew S. Goodwin

Name of applicant, assignee, or Registered Representative

(Signature)

December 2, 1992

(Date of Signature)

DEC 10 1992

GROUP 1500

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT

Dear Sir:

Please reconsider the above-identified application in view of the following remarks. These remarks are subdivided into a discussion of the claimed invention, and an analysis of the rejection, to facilitate an understanding of the significant differences between the cited art and the claimed invention.

Discussion of the Invention

A proper understanding of the invention is critical for appreciating the dissimilarities between the invention and the teachings of the cited references.

In a broad sense, the invention is a braided suture which contains dissimilar filaments of first and second fiber-forming materials. However, the proper characterization of the claimed suture goes far beyond this simple description.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS

DMI000235

The braided suture is made up of multifilament yarns. A multifilament yarn is a bundle of individual filaments which are integrated to form a single unit, that is, an individual multifilament yarn. The braided suture has a first and second set of these multifilament yarns in a braided construction. Each of the filaments of the first set of yarns is composed of a first fiber-forming material. Similarly, each of the filaments of the second set of yarns is composed of a second fiber-forming material.

The importance of the construction of the first and second set of yarns cannot be diminished. The braided construction is not accurately characterized by simply referring to a suture with filaments of dissimilar fiber-forming materials in a braided construction. Rather, filaments of a first fiber-forming material must be bundled to prepare a first set of multifilament yarns, and filaments of the second fiber-forming material must also be bundled to prepared the second set of multifilament yarns.

Once an understanding of the composition and construction of each set of first and second yarns is achieved, the importance of a further characterization of the braid construction can now be understood and appreciated. One yarn from the first set of yarns is in direct intertwining contact with a yarn from the second set of yarns. This limitation does not simply mean that the dissimilar filaments are fabricated into a braided construction, that is, dissimilar filaments are in "intertwining contact". Rather it is a multifilament yarn which is in direct intertwining contact with another multifilament yarn. Again, it is important to emphasize here that the multifilament yarns are integrated bundles of individual filaments, and it is this integrated bundle of filaments of a first fiber-forming material which is in direct intertwining

contact with another integrated bundle of individual filaments of a second fiber-forming material.

One way to accurately characterize the braided suture of this invention is to refer to it as a structured mechanical blend of dissimilar fiber-forming materials. The fiber-forming materials are first arranged into integrated bundles to form multifilament yarns and then these multifilament yarns are further arranged so that at least one yarn from the first set of yarns directly intertwines with a multifilament yarn from the second set of yarns. This can be contrasted with a random, braided construction where filaments of dissimilar fiber-forming materials are randomly braided with one another to form a braided suture.

The heterogeneous braids of this invention exhibit truly outstanding and surprising properties. The integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual multifilament yarns (see the specification at page 4, lines 30-33). In the preferred embodiment, each yarn from the first set of multifilament yarns is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar multifilament yarns (see the specification at page 6, lines 28-31, and claim 15). In this way, yarn compatibility can be further enhanced and the overall physical and biological properties of the heterogeneous braid can be further improved as well.

What is truly surprising with respect to the claimed heterogeneous braid construction is that certain bulk properties of the claimed braid are better than what one skilled in the art would expect. A skilled artisan would expect the properties of the braid to simply follow the "Rule of Mixtures", where the bulk property

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measured would be estimated to be a weighted average of its component properties. Upon studying the Examples in the specification, it will be noted that the bending rigidity of the heterogeneous braids in Examples 1 and 2 do not follow the Rule of Mixtures, but surprisingly show an enhanced bending rigidity relative to the weighted average of their filament components. This behavior is not achieved when dissimilar individual filaments are randomly braided to form the braided suture.

In setting forth the claimed invention, the heterogeneous braid does not encompass braided sutures with randomly braided individual filaments, as described in detail above. Further, the claimed heterogeneous braid could not be construed to cover known braids which have a core of longitudinally extending yarns composed of filaments of a first fiber-forming material, and a sheath of braided yarns composed of a second set of filaments of a dissimilar fiber-forming material. This braid construction does not fall within the scope of the claimed braid because these sheath yarns are not in direct intertwining contact with any of the core yarns. In other words, none of the sheath yarns are braided about a core yarn, but simply shroud the core yarns to form the sheath construction.

Analysis of the Rejection

1. Claims 21 and 23 were rejected under 35 USC §102(b) as being clearly anticipated by Doddi et al. ("Doddi"). Doddi does not anticipate the claimed suture, and therefore this rejection should be withdrawn.

The Examiner has correctly pointed out that Doddi does indeed disclose a surgical suture comprising filaments of two different polymers in a braided configuration (column 9, lines 47-56).

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However, as discussed in detail above, more is required to meet the limitations of the claimed suture than just a disclosure concerning filaments of two different polymers in a braided configuration. Doddi teaches nothing more than braiding individual filaments, and fails to provide any guidance as to how that braiding should be carried out. Therefore, one skilled in the art would be lead to believe that what Doddi had in mind was to simply braid individual filaments in a randomized fashion to fabricate a multifilament suture. It is important enough, however, to reemphasize again that the claimed braid requires the bundling of individual filaments into an integrated unit to form a multifilament yarn. It is this multifilament yarn which directly intertwines with another multifilament yarn to form Applicants' braid construction.

Since Doddi only teaches randomly braiding filaments of dissimilar fiber-forming materials, it does not anticipate the claimed braided suture. Doddi simply fails to enable one skilled in the art to construct a braided suture in the manner set forth by Applicants, and it is axiomatic that a reference which lacks enablement is deficient as a reference to anticipate a claimed invention. Accordingly, it is respectfully requested that the rejection of claims 21 and 23 under 35 USC §102(b) as being clearly anticipated by Doddi be withdrawn.

2. Claims 22 and 24 were rejected under 35 USC §103 as being unpatentable over Kaplan et al. ("Kaplan") taken with Doddi. The Examiner asserts it would have been obvious to substitute PET and PTFE fibers of Doddi for the filaments of Kaplan to arrive at Applicants' claimed suture. Applicants respectfully traverse this rejection for the reasons given below.

The Examiner correctly points out that Kaplan discloses a ligament prosthesis made from a core component and a braided sheath component as illustrated in Figures 3 and 4, and discussed at column 8, line 65, through column 9, line 34. However, Kaplan suffers from the same deficiencies as does Doddi, and therefore fails to teach or suggest the claimed braided suture.

Firstly, the Examiner has made specific reference to the Kaplan specification regarding the makeup of the core components and the sheath yarn component. The only component which has a braided construction is the sheath yarn component. It is clear from Figure 3 of Kaplan that none of the sheath yarn components are in direct intertwining contact with the core component. In other words, the sheath yarn component is a true "sheath" which shrouds the core but is not in any way integrally braided with the core. Therefore, since the core is not in a braided construction, its composition is irrelevant with respect to the claimed braided suture.

When the focus is shifted to the more relevant aspect of the Kaplan disclosure, specifically the sheath yarn component, the Examiner has correctly pointed out that the sheath yarn component may be "fabricated from individual filaments having more than two different chemical compositions, one or more of which optionally being non-absorbable". (Column 9, lines 25-28). However, Kaplan neither teaches nor suggests how his sheath yarn component is to be fabricated from these dissimilar individual filaments, nor is there any guidance to one skilled in the art as to how such dissimilar individual filaments are to be braided. Accordingly, just as was the case with the deficient Doddi reference, one skilled in the art could only be lead to randomly braid the dissimilar individual filaments into a braid construction.

The teaching of Kaplan once again lacks the essence of the claimed invention, which is: bundled filaments of a first fiber-forming material form a first set of a multifilament yarns, and at least one of these multifilament yarns is intertwined with a multifilament yarn composed of bundled filaments of a second fiber-forming material. To put it bluntly, Kaplan teaches randomized braiding, and the claimed suture sets forth a structured braid. This difference is not trivial, as pointed out with reference to the discussion of Applicant's specification, and particularly Examples 1 and 2.

It should also be pointed out here that even if Doddi and Kaplan were combined, their combined teachings would still fail to meet the limitations of the claimed braided suture. This is so because neither reference, taken singularly or in combination, discloses a structured braid set forth in the claims, but merely sets forth randomized braiding of individual filaments.

For all of the reasons given above, especially taken in light of the detailed discussion of the claimed braided suture and its surprising advantages, the rejection of claims 22 and 24 under 35 USC §103 as being unpatentable over Kaplan taken with Doddi is improper. Accordingly, it is respectfully requested that this rejection be withdrawn.

3. Applicants acknowledge with gratitude the withdrawal of the rejection of claims 21-24 under 35 USC §103 as being unpatentable over Burgess, expressed in the previous Office Action dated July 8, 1992. (Paper No. 3). It is presumed that Applicants' response to this rejection in their Amendment dated August 6, 1992, spelling out the distinctions between Burgess and the claimed

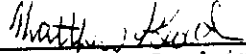
- 7 -

invention, clearly convinced the Examiner that the claimed surgical suture is patentable over this art.

4. The prior art made of record and not relied upon by the Examiner is duly noted, and does not affect the patentability of Applicants' claimed invention.

5. Since all formal requirements appear to have been met, and the claimed invention is patentable over the art of record or any other art of which Applicants are aware, Applicants respectfully solicit a Notice of Allowance at the Examiner's earliest convenience.

Respectfully submitted,


Matthew S. Goodwin
Attorney for Applicant
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December 2, 1992

Case Docket No.: ETH-782

In re application of Alastair W. Hunter et al.

Serial No. 838,311

Filed 21 December 19, 1992

For STABILIZED HETEROGENEOUS BRAIDS

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is an amendment in the above-identified application.

[] No additional fee is enclosed because this application was filed prior to October 25, 1965 (effective date of Public Law 89-83).

[X] No additional fee is required.

[X] One stamped, self-addressed postcard for the PTO Mail Room date stamp.

[] Petition For Extension of Time and charge to Deposit Account of Appropriate Fee.

The fee has been calculated as shown below.

CLAIMS AS AMENDED

(1)	(2)	(3)	(4)	(5)	(6)	(7)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL CLAIMS	* 24	minus	** 24	= 0	x \$22	= \$ 000.00
INDEP. CLAIMS	* 1	minus	*** 3	= 0	x \$74	= \$ 000.00
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT						\$ 000.00

* If the entry in Col.2 is less than the entry in Col.4, write "0" in Col.5.
 ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
 *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

[X] Charge \$ 000.00 to Deposit Account No. 10-750/ETH-782/MSG. Three copies of this sheet are enclosed.

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[] A check in the amount of \$ _____ is attached.

Matthew S. Goodwin
 Attorney of Record
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 December 2, 1992

DePuy Mitek, Inc. v. Arthrex, Inc.
 C.A. No.04-12457 PBS
DMI000243

In re application of Alastair W. Hunter et al.

Serial No. 838,511

Filed February 19, 1992

For STERILIZED HETEROGENEOUS BRAIDS

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

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CLAIMS AS AMENDED

(1)	(2)	(3)	(4)	(5)	(6)	(7)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
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TOTAL ADDITIONAL FEE FOR THIS AMENDMENT						\$ 000.00

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December 2, 1992

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000244

In re application of Alastair W. Hunter et al.

Serial No. 838,511

Filed 4 1992 February 19, 1992

For STERILIZED HETEROGENEOUS BRAIDS

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

DEC 10 1992

GPO 1500

Sir:

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[X] No additional fee is required.

[X] One stamped, self-addressed postcard for the PTO Mail Room date stamp.

[] Petition For Extension of Time and charge to Deposit Account of Appropriate Fee.

The fee has been calculated as shown below.

CLAIMS AS AMENDED

(1)	(2)	(3)	(4)	(5)	(6)	(7)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL CLAIMS	* 24	minus	** 24	= 0	x \$22	= \$ 000.00
INDEP. CLAIMS	* 1	minus	*** 3	= 0	x \$74	= \$ 000.00
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT						\$ 000.00

* If the entry in Col. 2 is less than the entry in Col. 4, write "0" in Col. 5.
 ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
 *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

[X] Charge \$ 000.00 to Deposit Account No. 10-750/ETH-782/MSG. Three copies of this sheet are enclosed.

[X] Please charge any additional fees in connection with the filing of this communication, or credit overpayment, to Deposit Account No. 10-750/ETH-782/MSG. Three copies of this sheet are enclosed.

[] A check in the amount of \$ _____ is attached.

 Attorney of Record
 Reg. No. 32,019

Matthew S. Goodwin
 Johnson & Johnson
 One Johnson & Johnson Plaza
 New Brunswick, New Jersey 08933-7003
 (908) 524-2791
 December 2, 1992

DePuy Mitek, Inc. v. Arthrex, Inc.
 C.A. No. 04-12457 PBS
DMI000245


**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

 Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/838,511	02/19/92	HUNTER	ETH-782

 ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

15N1

EXAMINER
RAYMOND, C

ART UNIT	PAPER NUMBER
1504	

DATE MAILED: 03/18/93

 This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

- ☐ This application has been examined
 ☒ Responsive to communication filed on Dec. 2, 1992
☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
 Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1 - 24 are pending in the application.

Of the above, claims 1 - 20 are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 21 - 24 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner, ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved, ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

 DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI000246

Serial No. 838,511

-2-

Art Unit 1504

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 21 is rejected under 35 U.S.C. § 102(e) as being anticipated by Kaplan et al.

Kaplan et al. discloses a connective tissue prosthesis comprising a braided sheath yarn component and a core yarn component. The braided sheath comprises braided filaments or braided filament bundles (column 9, lines 4-12). A sheath component containing filaments of different chemical compositions is specifically disclosed (column 9, lines 12-16). Claim 21 is therefore anticipated by Kaplan et al.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as

Serial No. 838,511

-3-

Art Unit 1504

prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 21-24 are rejected under 35 U.S.C. § 103 as being unpatentable over Doddi et al. taken with Kaplan et al.

Doddie et al. disclose a surgical suture comprising filaments of two different polymers in a braided configuration (column 9, lines 47-56). Suitable biocompatible, non absorbable filaments include PET and PTFE (column 9, lines 51-53).

Kaplan et al. discloses a ligament prosthesis comprising a core component and a braided sheath component. The core component is "made up of one or more biocompatible, essentially non-bioabsorbable..." filaments (column 9, lines 1-3). The sheath yarn component may be fabricated from one or more non-bioabsorbable fibers (column 9, lines 25-28). It would have been obvious to form the sheath component of the device of Kaplan et al. from PTFE and PET. PTFE is known to impart improved knot run down properties to sutures (see Block U.S. Pat. No. 3,527,650). PET is noted for its low cost and high strength. The core yarn component must be non-bioabsorbable (column 4, lines 45-46). Since PET is non-bioabsorbable, biocompatible and has the desirable properties noted above, its use as the core component would have been obvious. Claims 21 and 22 are therefore unpatentable over Doddie et al. taken

Serial No. 838,511

-4-

Art Unit 1504

with Kaplan et al.

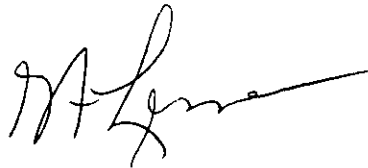
Kaplan et al. fail to disclose the prosthesis of their invention connected to a needle. Prosthesis are, however, implanted in the body using a needle. Claims 23 and 24 are therefore unpatentable over Doddi et al. taken with Kaplan et al.

Applicant's arguments with respect to claims 21-24 have been considered but are deemed to be moot in view of the new grounds of rejection.

Any inquiry concerning this communication should be directed to Chris Raimund at telephone number (703) 308-2374.



C. Raimund:pdw
February 25, 1993



GEORGE F. LESMES
SUPERVISORY PATENT EXAMINER
GROUP 150



ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.
Serial No.: 838,511 Art Unit: 1504
Filed : February 19, 1992 Examiner: C. Raimund
For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 4, 1993
(Date of Deposit)

Hal Brent Woodman
Name of applicant, assignee, or Registered Representative

Hal Brent Woodman
(Signature)

August 3, 1993
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Submitted herewith on Form PTO-1449, is a listing of documents known to the Applicants and/or their attorney in compliance with the requirements of 37 C.F.R. §1.56. Copies of these documents are also being submitted.

These documents are being submitted after the first Office Action. Accordingly, the Patent and Trademark Office is authorized to charge Account No. 10-750/ETH-782/HBW the appropriate fee under 37 C.F.R. §1.17(p) for the citation of these documents. Three copies of this statement are included.

CS14107 09/08/93 07838511

10-0750 140 126

200.00CH

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS

DMI000250

Consideration of the cited documents and making the same of record in the prosecution of the above-noted application are respectfully requested.

Respectfully submitted,

Hal B. Woodrow
Hal B. Woodrow
Reg. No. 32,501

JOHNSON & JOHNSON
One Johnson and Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976

ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.
Serial No.: 838,511 Art Unit: 1504
Filed : February 19, 1992 Examiner: C. Raimund
For : STERILIZED HETEROGENEOUS BRAIDS

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August 4, 1993
(Date of Deposit)

Hal Brent Woodrow
Name of applicant, assignee, or Registered Representative

Hal Brent Woodrow
(Signature)

August 3, 1993
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Submitted herewith on Form PTO-1449, is a listing of documents known to the Applicants and/or their attorney in compliance with the requirements of 37 C.F.R. §1.56. Copies of these documents are also being submitted.

These documents are being submitted after the first Office Action. Accordingly, the Patent and Trademark Office is authorized to charge Account No. 10-750/ETH-782/HBW the appropriate fee under 37 C.F.R. §1.17(p) for the citation of these documents. Three copies of this statment are included.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000252

Consideration of the cited documents and making the same of record in the prosecution of the above-noted application are respectfully requested.

Respectfully submitted,

Hal B. Woodrow
Hal B. Woodrow
Reg. No. 32,501

JOHNSON & JOHNSON
One Johnson and Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976

Sheet 1 of 1

Form 100-1449	Docket No.	Serial No.
	ETH-782	838,511
	Applicant	
	Alastair W. Hunter, et al.	
Filing Date		Group Art Unit
Feb. 19, 1992		1504

**INFORMATION DISCLOSURE CITATION
IN AN APPLICATION**

U.S. PATENT DOCUMENTS

Exam'r Init.	Document No.	Date	Name	Class	Sub Class	File Date
CWR	3,463,158	8/26/69	Edward Emil Schmitt, et al.	606	228	1/9/67
CWR	4,979,956	12/25/90	Thomas A. Silvestrini	623	13	7/10/89
CWR	3,636,956	1/25/72	Allan K. Schneider	128	335.5	5/13/70
CWR	4,141,087	2/27/79	Shalaby W. Shalaby, et al.	3	1	1/19/77
CWR	4,959,069	9/25/90	Karl W. Brennan, et al.	606	228	10/20/89

FOREIGN PATENT DOCUMENTS

Exam'r Init.	Document No.	Date	Country	Class	Sub Class	Translate Yes	No
CWR	GB 2 082 213	8/16/80	Great Britain			<input checked="" type="checkbox"/>	

OTHER REFERENCES (include author, title, date, pertinent pages, etc.)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI000254

Examiner	Date Considered
<i>Chen R. R.</i>	NOVEMBER 8, 1993

Examiners: Initial if citation considered, whether or not citation is in conformance with MPEP §609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.



DOCKET NO. ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

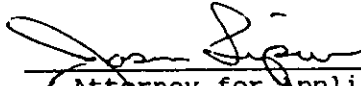
ASSOCIATE POWER OF ATTORNEY

Sir:

In the matter of the above-identified application, I hereby appoint Hal Woodrow (Reg. No.32,501), whose postal address is One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933-7003, my associate attorney to prosecute said application, to make alterations and amendments therein, to file continuing applications claiming the benefit of said application, to receive the patent and to transact all business in the Patent Office connected with said application.

I request all communications with respect to said application be addressed to Audley A. Ciamporzero, Jr., One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933-7003. All telephone calls should be directed to Hal Woodrow at (908) 524-2976.

Signed at New Brunswick, in the County of Middlesex and State of New Jersey, this 3rd day of August, 1993.



Attorney for Applicant(s)
Jason Lipow Reg. No. 25509

One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
DATED: August 3, 1993

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000255



CKET NO. ETH-782 *Copy 154*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 4, 1993
(Date of Deposit)

Hal B. Woodrow
Name of applicant, assignee, or Registered Representative

Hal B. Woodrow
(Signature)

August 3, 1993
(Date of Signature)

SEP 1 1993

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

PETITION FOR EXTENSION OF TIME
AND AUTHORIZATION TO CHARGE
DEPOSIT ACCOUNT THEREFOR

Dear Sir:

Applicant(s) petition(s) the Commissioner of Patents and Trademarks to extend the time for response to the Office Action dated March 18, 1993 for two (2) month(s) from June 18, 1993 to August 18, 1993. An Amendment responding to the aforesaid Office Action is being filed concurrently herewith.

Please charge Deposit Account No. 10-750/ETH-782/HBW in the name of Johnson & Johnson for the cost of filing this Petition. Three copies of this Petition are enclosed.

P 30003 08/30/93 07838511

Respectfully submitted,
10-0750 030 116 360.00CH

Hal B. Woodrow
Hal B. Woodrow
Reg. No. 32051
Attorney for Applicant(s)

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
DATE: August 4, 1993

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS

DMI000256

JCKET NO. ETH-782



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

No.: 838,511

Art Unit: 1504

Filed : February 19, 1992

Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 4, 1993
(Date of Deposit)

Hal B. Woodrow
Name of applicant, assignee, or Registered Representative

Hal B. Woodrow
(Signature)

August 3, 1993
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

SEP 1 1993

PETITION FOR EXTENSION OF TIME
AND AUTHORIZATION TO CHARGE
DEPOSIT ACCOUNT THEREFOR

Dear Sir:

Applicant(s) petition(s) the Commissioner of Patents and Trademarks to extend the time for response to the Office Action dated March 18, 1993 for two (2) month(s) from June 18, 1993 to August 18, 1993. An Amendment responding to the aforesaid Office Action is being filed concurrently herewith.

Please charge Deposit Account No. 10-750/ETH-782/HBW in the name of Johnson & Johnson for the cost of filing this Petition. Three copies of this Petition are enclosed.

Respectfully submitted,

Hal B. Woodrow
Hal B. Woodrow
Reg. No. 32051
Attorney for Applicant(s)

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
DATE: August 4, 1993

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000257



ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511

Art Unit: 1504

Filed : February 19, 1992

Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 4, 1993
(Date of Deposit)

Neil B. Woodrow
Name of Applicant, Assignee, or Registered Representative

Neil B. Woodrow
(Signature)

August 3, 1993
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT

Dear Sir:

This amendment is responsive to the Office Action of March 18, 1993.

IN THE CLAIMS

Please amend claim 2 as follows:

(Once Amended)

CM 1. A surgical suture [comprising] consisting essentially of a [the] heterogeneous braid [of claim 1] composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

PI a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

PI b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

PI c) optionally a core.

26

CLAIM 2

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000258

REMARKS

6. Please note that the attorney prosecuting this application for the assignee, Johnson & Johnson, is now Hal Brent Woodrow (Reg. No. 32,501). This change has been authorized by the Associated Power Attorney submitted herewith. No change in the address for correspondence is necessary.

Claim 21 has been amend to place this claim in proper form for allowance. Claim 21 as amended claims a heterogeneous braid composed of a first and second set of yarns. The first set of yarns are made of a fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP, and PE materials. The second set of yarns are made of a fiber-forming material selected from the group consisting PET, nylon and aramid materials. Support for there amendments may be found in the specification on page 4, lines 12-22 and page 8, lines 3-23. Accordingly, applicants request entry of this amendment and reconsideration of claim 21.

The rejection of claim 21 under 35 U.S.C. §102(e) as being anticipated by Kaplan et al. has been reviewed. However, applicants respectfully submit that claim 21 as amended is not anticipated by Kaplan. Kaplan, as stated by the Examiner, describes a connective tissue prosthesis comprising a braided sheath yarn component and a core yarn component. The sheath yarn being a biocompatible yarn that is bioabsorbable or semi-bioabsorbable (column 9 lines 10-12). In one embodiment the sheath yarn could also contain a non-bioabsorbable yarn of one or more chemical composition (column 9 line 25-27). Claim 21 as amended does not claim a sheath yarn composed of a bioabsorbable yarn. Accordingly, Kaplan et al. does not anticipate claim 21 under 35 U.S.C. § 102(e). Therefore, applicants request reconsideration and withdrawal of the rejection of claim 21 as being anticipated by Kaplan et al.

Applicants have also reviewed the rejection of claims 21-24 under 35 U.S.C. § 103 as being unpatentable over Doddi et al. taken with Kaplan et al. However, applicants respectfully submit that claims 21-24 are patentable over these documents.

Doddi et al. describes (column 9, lines 46-56) multifilament sutures composed of p-dioxanone and/or 1,4 dioxepan-2-one and alkyl substituted derivatives that may be woven, braided or knitted, either alone or in combination with nonabsorbable fibers. Although Doddi is a significant contribution to the art, Doddi does not describe heterogeneous braids formed from a first set of yarn composed of a plurality of filaments formed from materials selected

- 2 -

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS

DMI000259

from the group consisting of PTFE, FEP, PFA PVDF, PETFE, PP and PE; and a second set of yarn composed from a plurality of filaments formed from materials selected from the group consisting of PET, nylon and aramid. Accordingly, Doddi alone would not render the present invention obvious.

Kaplan et al. as discussed previously describes a prosthesis comprising a core component and a braided sheath component. The sheath component which is designed to "erode over time" (column 9, line 52) to leave only the nonabsorbable core component. The sheath, however, may optionally have, in addition to the bioabsorbable sheath yarn, one or more non-bioabsorbable filaments. Applicants, therefore, respectfully submit that Kaplan does not suggest or disclose combining a first set of nonabsorbable yarns (i.e. PTFE) and a second set of nonabsorbable yarn (i.e. PET). In fact, Kaplan teaches away from this combination.

In column 2, Kaplan describe one of the objects of their invention as being "a prosthesis being formed of a composite yarn wherein an elastic core yarn is wrapped with a relatively inelastic, bioabsorbable or semi-absorbable sheath yarn so as to exhibit the stress-strain properties of natural tissue" (column 2, lines 36-41). In column 4, Kaplan describes fluorinated hydrocarbons, polypropylene and polyethylene as elastic core polymers as opposed to the inelastic sheath polymers desired in the sheath. Thus, Kaplan appears to suggest that the sheath yarns listed by the applicant in claim 21 should not be used as in sheaths. Applicants respectfully submit that in view of Kaplan teaching away from the present invention that the combination of Kaplan with Doddi does not render the present invention obvious. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 21-24.

The citation of Block (U.S. Patent No. 3,527,650) has also been considered, but is respectfully submitted to be non-analogous art. Block describes the use of PTFE particles on the external surface of a PET suture as a lubricant. Block, however, does not suggest or disclose PTFE fiber as having a lubricating effect. Therefore, Block's use of PTFE particles does not suggest or disclose the use of PTFE fibers in braids.

Applicants also wish to alert the Examiner to the applicants' intent to change the inventorship because of the reduced scope of the claims. Dennis D. Jamiolkowski will no longer appear as an inventor if the present claims are allowed. Papers to effectuate this changed inventorship will be submitted when one or more of the present claims are indicated to be allowable.

Respectfully requested,

Hal Brent Woodrow
Hal B. Woodrow
Reg. No. 32,501

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
Date: August 31 1995



GP 1504

ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511

Art Unit: 1504

Filed : February 19, 1992

Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

RECEIVED GROUP 150

NOV 16 1993

November 9, 1993

(Date of Deposit)

Hal Brent Woodrow

Name of applicant, assignee, or Registered Representative:

Hal Brent Woodrow

(Signature)

November 9, 1993

(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

11-24-93
7560
Raimund

SUPPLEMENTAL AMENDMENT

Dear Sir:

This Supplemental Amendment is an amendment to the Amendment submitted on August 4, 1993.

REMARKS

Applicants have noticed that the Amendment of August 4, 1993 under the heading "In The Claims" states, "Please amend claim 2 as follows:", however, the claim designated as being amended is claim

Noted - checked by Examiner -

MA Lerner (SPE)

12-30-93

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS

DMI000262

USSN 838,511

21. Applicants respectfully request this sentence be changed to read "Please amend claim 21 as follows:".

Hal Brent Woodrow

Hal Brent Woodrow
Reg. No. 32,501
Attorney for Applicant(s)

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
November 9, 1993

- 2 -



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	INVENTOR	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
---------------	-------------	----------	-----------------------	---------------------

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933 7003

15N1/11.8

EXAMINER

ARTWORK PAPER NUMBER

11/24/03

DATE MAILED:

NOTICE OF ALLOWABILITY

PART I

1. ☒ This communication is responsive to the Amendment filed August 9, 1993.
2. ☒ All the claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.
3. ☒ The allowed claims are 21, 23, 24, 7, 8, 10-12, 14, 18-20.
4. ☐ The drawings filed on _____ are acceptable.
5. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received. ☐ not been received. ☐ been filed in parent application Serial No. _____, filed on _____.
6. ☒ Note the attached Examiner's Amendment.
7. ☐ Note the attached Examiner Interview Summary Record, PTOL-413.
8. ☐ Note the attached Examiner's Statement of Reasons for Allowance.
9. ☐ Note the attached NOTICE OF REFERENCES CITED, PTO-892.
10. ☒ Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

PART II

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

1. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
2. ☐ APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
- a. ☐ Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No. _____ CORRECTION IS REQUIRED.
- b. ☐ The proposed drawing correction filed on _____ has been approved by the examiner. CORRECTION IS REQUIRED.
- c. ☐ Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
- d. ☐ Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

Attachments:

- ☒ Examiner's Amendment
- ☐ Examiner Interview Summary Record, PTOL-413
- ☐ Reasons for Allowance
- ☐ Notice of References Cited, PTO-892
- ☒ Information Disclosure Citation, PTO-1449

- ☐ Notice of Informal Application, PTO-152
- ☐ Notice re Patent Drawings, PTO-948
- ☐ Listing of Bonded Draftsmen
- ☐ Other

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000264

Serial Number: 07/838,511

-2-

Art Unit: 1504

Part III EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Hal B. Woodrow on November 15, 1993.

Permission was given to amend the claims as follows:

Cancel claims 1, 6, 9, 13, 15, 16, 17 and 22.

In claims 7, 8, 10, 11, 12, 14, 18, 19 and 20, line 1, change "heterogeneous braid" to "surgical suture".

In claim 7, line 1, change "6" to "21".

In claim 10, line 1, change "9" to "8".


In claim 14, line 1, change "13" to "12".

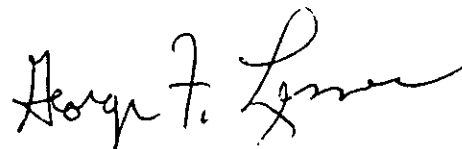
In claim 18, line 1, change "17" to "14".

In claim 20, line 1, change "1" to "21".

In claim 24, line 1, change "22" to "14".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Raimund whose telephone number is (703) 308-2374.


Chris Raimund/cwr
November 15, 1993


GEORGE F. LESMES
SUPERVISORY PATENT EXAMINER
GROUP 150


**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: Box ISSUE FEE
COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

ROBERT L. WINIEN
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08923-7000

**NOTICE OF ALLOWANCE
AND ISSUE FEE DUE**

- ☐ Note attached communication from the Examiner
☐ This notice is issued in view of applicant's communication filed _____

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
07/008,511	01/19/92	012	ARMSTRONG, J.	10/11/92
First Named Applicant	UNITED STATES OF AMERICA, ALABAMA			

TITLE OF INVENTION: STERILIZED HETEROPHASEOUS BRANES

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
ETH-732	065-131.000	567	UTILITY	NO	\$1175.00	04/18/93

THE FEE DUE IS THE AMOUNT IN EFFECT AT THIS TIME. IF THE AMOUNT OF THE ISSUE FEE INCREASES PRIOR TO PAYMENT, APPLICANT WILL BE NOTIFIED OF THE BALANCE OF ISSUE FEE DUE.

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.

PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

- I. Review the SMALL ENTITY Status shown above.
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the patent and Trademark Office of the change in status, or
B. If the Status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

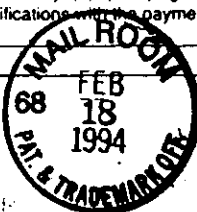
- A. Pay FEE DUE shown above, or
B. File verified statement of Small Entity Status before, or with, pay of 1/2 the FEE DUE shown above.

- II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.
- III. All communications regarding this application must give series code (or filing date) and serial number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to contrary.

IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B—ISSUE FEE TRANSMITTAL

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE. Blocks 2 through 6 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advances orders and notification of maintenance fees will be mailed to address entered in Block 1 unless you direct otherwise, by: (a) specifying a new correspondence address in Block below, or (b) providing the PTO with a separate "FEE ADDRESS" for maintenance fee notifications with the payment of Issue Fee or thereafter. See reverse for Certificate of Mailing.

1. CORRESPONDENCE ADDRESS	2. INVENTOR(S) ADDRESS CHANGE (Complete only if there is a change)
 <p>1500 1111</p> <p>JOHNSON PLAZA</p> <p>1000 1111</p>	INVENTOR'S NAME
	Street Address
	City, State and ZIP Code
	CO-INVENTOR'S NAME
	Street Address
	City, State and ZIP Code
	<input type="checkbox"/> Check if additional changes are on reverse side

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
First Named Applicant				

TITLE OF INVENTION

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPL. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
ETH-280	606-231.000	567	UTILITY	000	1111.00	02/18/94

3. Correspondence address change (Complete only if there is a change)	4. For printing on the patent front page, list the names of not more than 3 registered patent attorneys or agents OR alternatively, the name of a firm having as a member a registered attorney or agent. If no names are listed, no name will be printed.
<p>02/22/94 07838511/-</p> <p>02/22/94 07838511/-</p>	<p>Hal Brent Woodrow</p> <p>170.00CH</p> <p>30.00CH</p>

DO NOT USE THIS SPACE

5. ASSIGNMENT DATA TO BE PRINTED ON THE PATENT (print or type)		6a. The following fees are enclosed:	
(1) NAME OF ASSIGNEE:	Recorded- 2/19/92 Reel-6023	<input type="checkbox"/> Issue Fee	<input type="checkbox"/> Advanced Order - # of Copies (Minimum of 10)
(2) ADDRESS (CITY & STATE OR COUNTY)	Frame-941	6b. The following fees should be changed to:	
(3) STATE OF INCORPORATION, IF ASSIGNEE IS A CORPORATION	Ohio	DEPOSIT ACCOUNT NUMBER 10-0750	
<p>A <input type="checkbox"/> This application is NOT assigned.</p> <p><input checked="" type="checkbox"/> Assignment is being previously submitted to the Patent and Trademark Office.</p> <p><input type="checkbox"/> Assignment is being submitted under separate cover. Assignments should be directed to Box ASSIGNMENTS.</p> <p>PLEASE NOTE: Unless an assignee is identified in Block 5, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.</p>		<p>(ENCLOSED PART C)</p> <p><input checked="" type="checkbox"/> Issue Fee <input checked="" type="checkbox"/> Advanced Order - # of Copies 10 (Minimum of 10)</p> <p><input type="checkbox"/> Any Delinquencies in Enclosed Fees</p>	
		The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee to the application identified above.	
		(Signature of party in interest of record)	(Date)
		32,501 Hal Brent Woodrow	2/16/94
NOTE: This Issue Fee will not be collected from anyone other than the applicant, a registered attorney or agent, or the assignee or other party in interest as shown by the records of the Patent and Trademark Office.			

TRANSMIT THIS FORM WITH FEE CERTIFICATE OF MAILING ON REVERSE

PTOL-858 (REV.7-92)(OMB Clearance is pending)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000267

Certificate of Mailing

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

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Washington, D.C. 20231

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PATENT & TRADEMARK OFC
IRSB DIVISION

on February 16, 1994
(Date)

Hal Brent Woodrow
(Signature)

Hal Brent Woodrow
(Typed or Printed Name)

February 16, 1994
(Date)

Note: If this certificate of mailing is used, it can only be used to transmit the Issue Fee. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

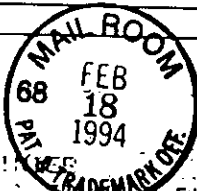
This form is estimated to take 20 minutes to Complete. Time will vary depending upon the needs of the individual applicant. Any comments on the amount of time you require to complete this form should be sent to the Office of Management and Organization, Patent and Trademark Office, Washington, D.C. 20231 and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS

DMI000268

PART B—ISSUE FEE TRANSMITTAL

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1. CORRESPONDENCE ADDRESS		2. INVENTOR(S) ADDRESS CHANGE (Complete only if there is a change)	
 <p>ROBERT L. MITER ONE WASHINGTON PLAZA NEW BRUNSWICK, NJ 08902-7000</p>		<p>INVENTOR'S NAME</p> <p>Street Address</p> <p>City, State and ZIP Code</p> <p>CO-INVENTOR'S NAME</p> <p>Street Address</p> <p>City, State and ZIP Code</p> <p><input type="checkbox"/> Check if additional changes are on reverse side</p>	

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
First Named Applicant				
TITLE OF INVENTION				

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPL. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
ETH-000	606-001.000	507	UTILITY	NO	\$1170.00	02/18/94

Note: If the certificate of mailing is used for the issue fee, the certificate cannot be used for any other purpose. Each additional paper, such as an assignment or form, must have its own certificate of mailing.

3. Correspondence address change (Complete only if there is a change)	4. For printing on the patent front page, list the names of not more than 3 registered patent attorneys or agents OR alternatively, the name of a firm having as a member a registered attorney or agent. If no name is listed, no name will be printed.
	1. Hal Brent Woodrow
	2. _____
	3. _____

DO NOT USE THIS SPACE

5. ASSIGNMENT DATA TO BE PRINTED ON THE PATENT (print or type)		6. The following fees are enclosed:	
(1) NAME OF ASSIGNEE Ethicon, Inc. Recorded 2/19/92 Reel-6023		<input type="checkbox"/> Issue Fee <input type="checkbox"/> Advanced Order - # of Copies _____	
(2) ADDRESS (CITY & STATE OR COUNTRY) Somerville, N.J.		(3) The following fees should be changed to: (Minimum of 10)	
(3) STATE OF INCORPORATION, IF ASSIGNEE IS A CORPORATION Ohio		90 DEPOSIT ACCOUNT NUMBER 10-0750	
A. <input type="checkbox"/> This application is NOT assigned.		(ENCLOSED PART C)	
<input checked="" type="checkbox"/> Assignment is being previously submitted to the Patent and Trademark Office.		<input checked="" type="checkbox"/> Issue Fee <input checked="" type="checkbox"/> Advanced Order - # of Copies 10	
<input type="checkbox"/> Assignment is being submitted under separate cover. Assignments should be directed to Box ASSIGNMENTS.		<input type="checkbox"/> Any Deficiencies in Enclosed Fees	
PLEASE NOTE: Unless an assignee is identified in Block 5, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.		The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee to the application identified above.	
		(Signature of party in interest of record)	
		32,501 Hal Brent Woodrow 2/16/94	
		NOTE: If the Issue Fee will not be accepted from anyone other than the applicant, a registered attorney or agent, or the assignee or other party in interest as shown by the records of the Patent and Trademark Office.	

TRANSMIT THIS FORM WITH FEE-CERTIFICATE OF MAILING ON REVERSE

PTOL-858 (REV. 7-82) (OMB Clearance is pending)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI000269

PART B—ISSUE FEE TRAINING

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Commissioner of Patents and Trademarks
Washington, D.C. 20231

ON	February 16, 1994	(Date)
(Signature)	Hal Brent Woodward	
(Typed or Printed Name)	Hal Brent Woodward	
(Date)	February 16, 1994	

Note: If this certificate of mailing is used, it can only be used to transmit the Issue Fee. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI000270

This form is estimated to take 20 minutes to Complete. Time will vary depending upon the needs of the individual applicant. Any comments on the amount of time you require to complete this form should be sent to the

Office of Management and Organization, Patent and Trademark Office, Washington, D.C. 20231, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

35,201
Hal Brent Woodward
Commissioner of Patents and Trademarks
Washington, D.C. 20231

ASSIGNMENT DATA TO BE PRINTED
NAME OF APPLICANT
NAME OF INVENTOR
NAME OF ATTORNEY
NAME OF AGENT
NAME OF FIRM
NAME OF ADDRESS
NAME OF CITY
NAME OF STATE
NAME OF ZIP
NAME OF COUNTRY



81504
[Handwritten signature]

ETH: 782
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Alastair W. Hunter, Dennis D. Jamiolkowski
and Arthur Taylor, Jr.

Serial No. 07/838,511

Group No. 1504

Filed: February 19, 1992

Examiner: C. Raimund

For: **STERILIZED HETEROGENOUS BRAIDS**

CERTIFICATE OF MAILING (37 CFR 1.8(a))

RECEIVED

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231.

DEC 08 1993
GROUP 1504

Hal Brent Woodrow

Name of Person Mailing Paper

Date: November 22, 1993

Hal Brent Woodrow
Signature of Person Mailing Paper

Commissioner of Patents and Trademarks
Washington, D. C. 20231

12-6-93

7560

Raimund

**AMENDMENT, PETITION AND FEE DELETING CORRECTLY NAMED
ORIGINAL PERSON(S) WHO ARE NOT INVENTOR(S) OF INVENTION NOW
BEING CLAIMED (37 CFR 1.48(b))**

1. This amendment and petition under 37 CFR 1.48(b) is to delete the name(s) of the following person(s) originally named as inventor(s) of the invention now being claimed:

Dennis D. Jamiolkowski

2. Claims Now On File

The claims in this application are as follows:

[] originally filed claim(s) _____
[] originally filed claims _____ as amended on _____

[] claim(s) _____ filed on _____

[X] claim(s) 21-24 filed on February 19, 1992 as amended on August 4, 1993 and amended by the Examiner's Amendment of November 15, 1993

P 30079

10-0750

170-0000

OK to enter -
MAZ

USSN 07/838,511

[X] claims 25-33 added by the Examiner's Amendment of November 15, 1993

3. DILIGENCE

This amendment and petition is being filed

[X] diligently after discovery that any claim(s) for which the above-named inventor who is being deleted are now no longer the inventor of the subject matter being claimed.

4. STATUS OF INVENTORSHIP AFTER AMENDMENT

[] Attached is an explanation of the facts, including the ownership of all the claim(s) at the time the last claimed invention was made (Declaration of Inventorship and Common Ownership of Claims in Application).

5. FEE (37 CFR 1.17(h))

The fee required is paid as follow:

[X] charge Account No. 10-750/HBW/ETH-782 for any fee deficiency

[X] charge Account No. 10-750/HBW/ETH-782 the sum of \$130.00

Hal Brent Woodrow
Hal Brent Woodrow
Reg. No. 32,501

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
November 22, 1993

PTO UTILITY GRANT

Paper Number 14

The
United
States
of
America

The Commissioner of Patents
and Trademarks

*Has received an application for a patent
for a new and useful invention. The title
and description of the invention are en-
closed. The requirements of law have
been complied with, and it has been de-
termined that a patent on the invention
shall be granted under the law.*

Therefore, this

United States Patent

*Grants to the person or persons having
title to this patent the right to exclude
others from making, using or selling the
invention throughout the United States
of America for the term of seventeen
years from the date of this patent, sub-
ject to the payment of maintenance fees
as provided by law.*



Bence Lehman

Commissioner of Patents and Trademarks

Santha Z. Morton
Attest

PTO-1584

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000273

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark OfficeAddress COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	INVENTOR'S NAME	ATTORNEY'S NAME
4778 201511	02/19/92	HUNTER	1,141,111

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

15N170527

EXAMINER

ART UNIT	PAPER NUMBER
----------	--------------

1504

DATE MAILED 05/27/94

- A. ☐ The petition filed _____ under 37 CFR 1.312(b) is granted.
The paper has been forwarded to the examiner for consideration on the merits.

- B. ☒ The amendment filed 2/16/94 under 37 CFR 1.312 has been considered, and has been:

1. ☐ entered
2. ☒ entered as directed to matters of form not affecting the scope of the invention (0.3311).
3. ☐ disapproved. A report appears below.
4. ☐ entered in part. A report appears below.

Report:

CELESTE L. HARRIS
SUPERVISOR OF EXAMINERS
GROUP 150

PLEASE FURNISH YOUR ZIP CODE IN ALL CORRESPONDENCE

Fig. 2a, 1789

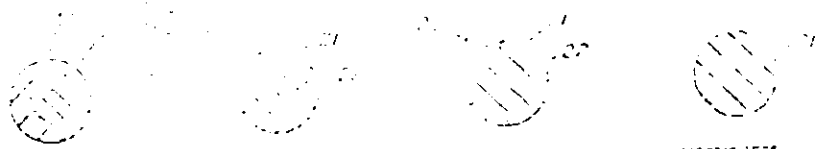


FIG. 2a, 1789

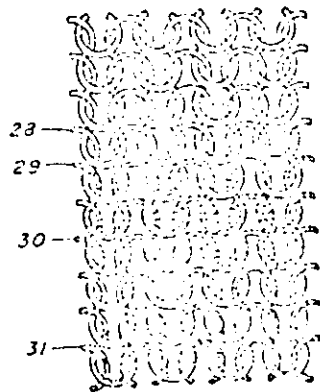


25-NON-ABSORBABLE

FIG. 5

FIG. 6

FIG. 7



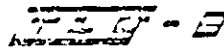
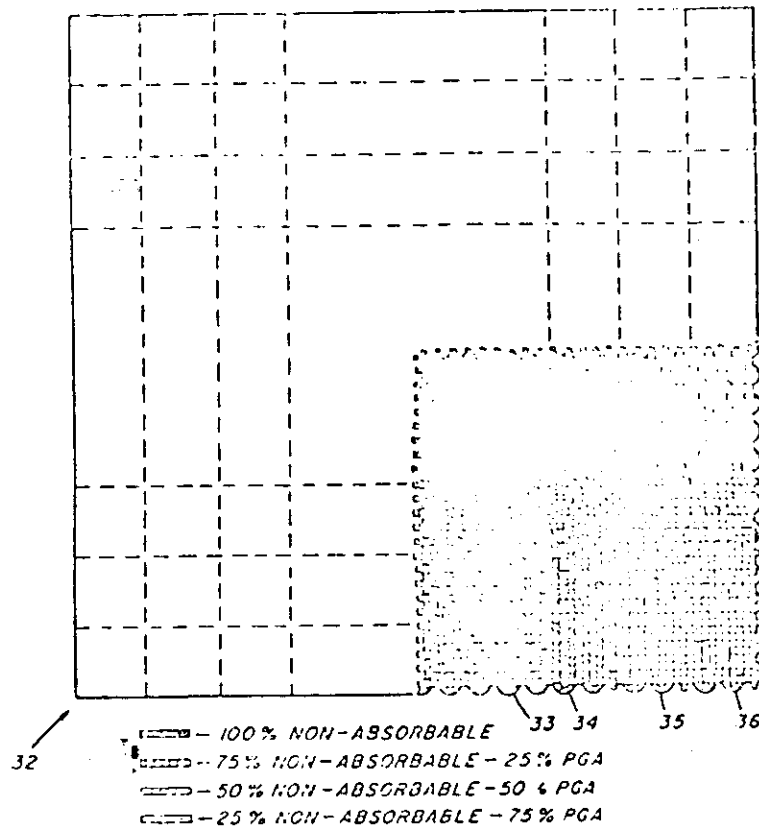
- - 100% NON-ABSORBABLE
- ▨ - 75% NON-ABSORBABLE - 25% PGA
- ▤ - 50% NON-ABSORBABLE - 50% PGA
- ▥ - 25% NON-ABSORBABLE - 75% PGA

FIG. 5

INVENTORS:
EDWARD EMIL SCHMITT
RUCCO ALBERT POLISTINA
BY

Samuel Brandt Helber
ATTORNEY

FIG. 1 is a schematic diagram of a rectangular mesh structure 32. The mesh structure 32 is composed of a grid of rectangular cells. A portion of the mesh structure 32, specifically the bottom right corner, is shaded with a stippled pattern, indicating a specific material composition. This shaded area is labeled with reference numerals 33, 34, 35, and 36.



INVENTORS
EDWARD EMIL SCHMITT
ROCCO ALBERT POLISTINA
BY

Samuel Brandt
ATTORNEY

U.S. PATENT AND TRADEMARK OFFICE
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 AUG 11 2006

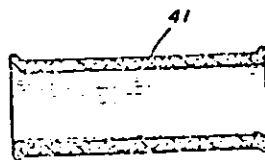
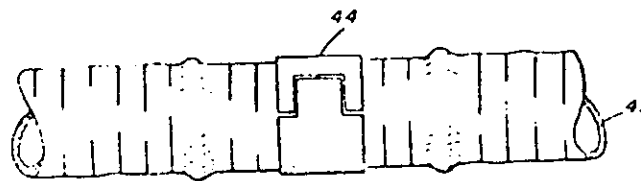
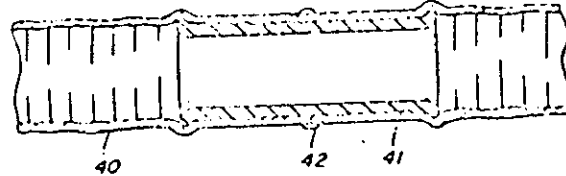
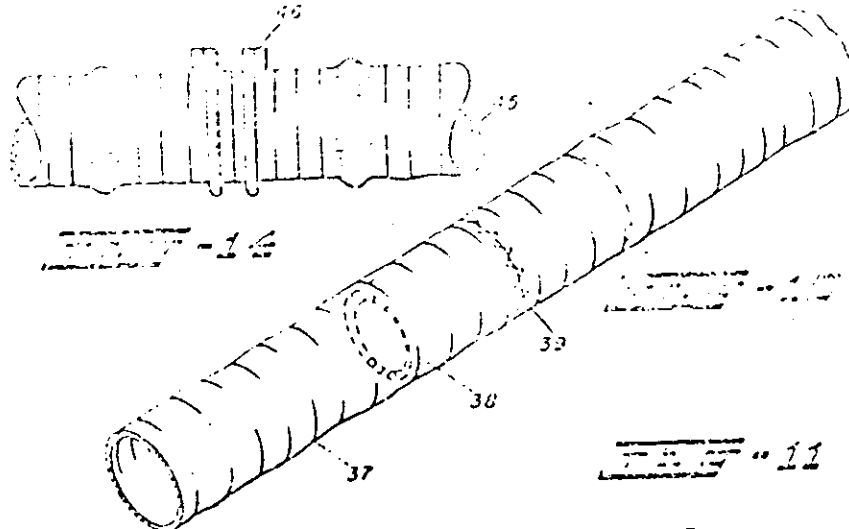


FIG. 12

INVENTORS
 EDWARD EMIL SCHMITT
 ROCCO ALBERT POLISTINA
 BY
Samuel Brinkman
 ATTORNEY

2004-08-11 10:00 AM
 2004-08-11 10:00 AM



FIG. 16

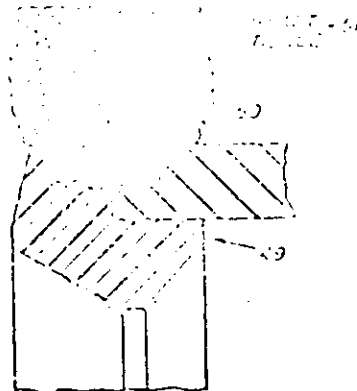


FIG. 15

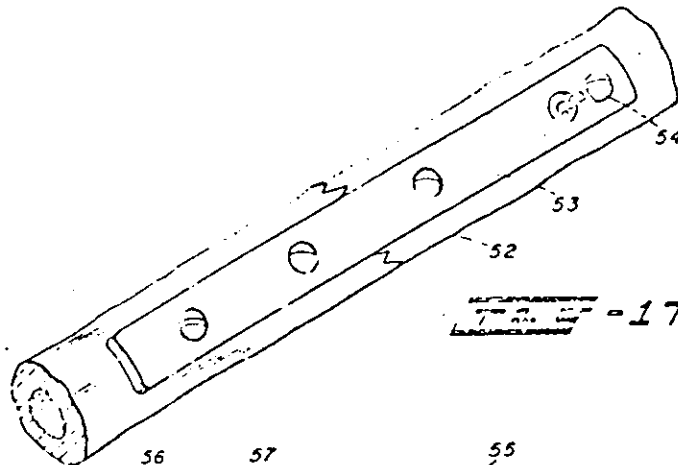


FIG. 17

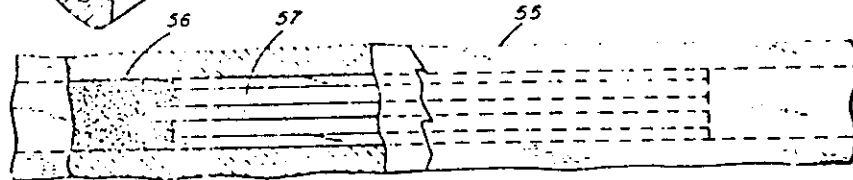


FIG. 18

INVENTORS,
 EDWARD EMIL SCHMITT
 ROCCO ALBERT POLISTINA
 BY

Samuel Brandt Trepp
 ATTORNEY

U.S. 44,120-334

10. *Re: 11-11-1968, 11-12-1968, 11-13-1968, 11-14-1968, 11-15-1968, 11-16-1968, 11-17-1968, 11-18-1968, 11-19-1968, 11-20-1968, 11-21-1968, 11-22-1968, 11-23-1968, 11-24-1968, 11-25-1968, 11-26-1968, 11-27-1968, 11-28-1968, 11-29-1968, 11-30-1968, 12-1-1968, 12-2-1968, 12-3-1968, 12-4-1968, 12-5-1968, 12-6-1968, 12-7-1968, 12-8-1968, 12-9-1968, 12-10-1968, 12-11-1968, 12-12-1968, 12-13-1968, 12-14-1968, 12-15-1968, 12-16-1968, 12-17-1968, 12-18-1968, 12-19-1968, 12-20-1968, 12-21-1968, 12-22-1968, 12-23-1968, 12-24-1968, 12-25-1968, 12-26-1968, 12-27-1968, 12-28-1968, 12-29-1968, 12-30-1968, 12-31-1968, 1-1-1969, 1-2-1969, 1-3-1969, 1-4-1969, 1-5-1969, 1-6-1969, 1-7-1969, 1-8-1969, 1-9-1969, 1-10-1969, 1-11-1969, 1-12-1969, 1-13-1969, 1-14-1969, 1-15-1969, 1-16-1969, 1-17-1969, 1-18-1969, 1-19-1969, 1-20-1969, 1-21-1969, 1-22-1969, 1-23-1969, 1-24-1969, 1-25-1969, 1-26-1969, 1-27-1969, 1-28-1969, 1-29-1969, 1-30-1969, 1-31-1969, 2-1-1969, 2-2-1969, 2-3-1969, 2-4-1969, 2-5-1969, 2-6-1969, 2-7-1969, 2-8-1969, 2-9-1969, 2-10-1969, 2-11-1969, 2-12-1969, 2-13-1969, 2-14-1969, 2-15-1969, 2-16-1969, 2-17-1969, 2-18-1969, 2-19-1969, 2-20-1969, 2-21-1969, 2-22-1969, 2-23-1969, 2-24-1969, 2-25-1969, 2-26-1969, 2-27-1969, 2-28-1969, 2-29-1969, 2-30-1969, 3-1-1969, 3-2-1969, 3-3-1969, 3-4-1969, 3-5-1969, 3-6-1969, 3-7-1969, 3-8-1969, 3-9-1969, 3-10-1969, 3-11-1969, 3-12-1969, 3-13-1969, 3-14-1969, 3-15-1969, 3-16-1969, 3-17-1969, 3-18-1969, 3-19-1969, 3-20-1969, 3-21-1969, 3-22-1969, 3-23-1969, 3-24-1969, 3-25-1969, 3-26-1969, 3-27-1969, 3-28-1969, 3-29-1969, 3-30-1969, 3-31-1969, 4-1-1969, 4-2-1969, 4-3-1969, 4-4-1969, 4-5-1969, 4-6-1969, 4-7-1969, 4-8-1969, 4-9-1969, 4-10-1969, 4-11-1969, 4-12-1969, 4-13-1969, 4-14-1969, 4-15-1969, 4-16-1969, 4-17-1969, 4-18-1969, 4-19-1969, 4-20-1969, 4-21-1969, 4-22-1969, 4-23-1969, 4-24-1969, 4-25-1969, 4-26-1969, 4-27-1969, 4-28-1969, 4-29-1969, 4-30-1969, 5-1-1969, 5-2-1969, 5-3-1969, 5-4-1969, 5-5-1969, 5-6-1969, 5-7-1969, 5-8-1969, 5-9-1969, 5-10-1969, 5-11-1969, 5-12-1969, 5-13-1969, 5-14-1969, 5-15-1969, 5-16-1969, 5-17-1969, 5-18-1969, 5-19-1969, 5-20-1969, 5-21-1969, 5-22-1969, 5-23-1969, 5-24-1969, 5-25-1969, 5-26-1969, 5-27-1969, 5-28-1969, 5-29-1969, 5-30-1969, 5-31-1969, 6-1-1969, 6-2-1969, 6-3-1969, 6-4-1969, 6-5-1969, 6-6-1969, 6-7-1969, 6-8-1969, 6-9-1969, 6-10-1969, 6-11-1969, 6-12-1969, 6-13-1969, 6-14-1969, 6-15-1969, 6-16-1969, 6-17-1969, 6-18-1969, 6-19-1969, 6-20-1969, 6-21-1969, 6-22-1969, 6-23-1969, 6-24-1969, 6-25-1969, 6-26-1969, 6-27-1969, 6-28-1969, 6-29-1969, 6-30-1969, 7-1-1969, 7-2-1969, 7-3-1969, 7-4-1969, 7-5-1969, 7-6-1969, 7-7-1969, 7-8-1969, 7-9-1969, 7-10-1969, 7-11-1969, 7-12-1969, 7-13-1969, 7-14-1969, 7-15-1969, 7-16-1969, 7-17-1969, 7-18-1969, 7-19-1969, 7-20-1969, 7-21-1969, 7-22-1969, 7-23-1969, 7-24-1969, 7-25-1969, 7-26-1969, 7-27-1969, 7-28-1969, 7-29-1969, 7-30-1969, 7-31-1969, 8-1-1969, 8-2-1969, 8-3-1969, 8-4-1969, 8-5-1969, 8-6-1969, 8-7-1969, 8-8-1969, 8-9-1969, 8-10-1969, 8-11-1969, 8-12-1969, 8-13-1969, 8-14-1969, 8-15-1969, 8-16-1969, 8-17-1969, 8-18-1969, 8-19-1969, 8-20-1969, 8-21-1969, 8-22-1969, 8-23-1969, 8-24-1969, 8-25-1969, 8-26-1969, 8-27-1969, 8-28-1969, 8-29-1969, 8-30-1969, 8-31-1969, 9-1-1969, 9-2-1969, 9-3-1969, 9-4-1969, 9-5-1969, 9-6-1969, 9-7-1969, 9-8-1969, 9-9-1969, 9-10-1969, 9-11-1969, 9-12-1969, 9-13-1969, 9-14-1969, 9-15-1969, 9-16-1969, 9-17-1969, 9-18-1969, 9-19-1969, 9-20-1969, 9-21-1969, 9-22-1969, 9-23-1969, 9-24-1969, 9-25-1969, 9-26-1969, 9-27-1969, 9-28-1969, 9-29-1969, 9-30-1969, 10-1-1969, 10-2-1969, 10-3-1969, 10-4-1969, 10-5-1969, 10-6-1969, 10-7-1969, 10-8-1969, 10-9-1969, 10-10-1969, 10-11-1969, 10-12-1969, 10-13-1969, 10-14-1969, 10-15-1969, 10-16-1969, 10-17-1969, 10-18-1969, 10-19-1969, 10-20-1969, 10-21-1969, 10-22-1969, 10-23-1969, 10-24-1969, 10-25-1969, 10-26-1969, 10-27-1969, 10-28-1969, 10-29-1969, 10-30-1969, 10-31-1969, 11-1-1969, 11-2-1969, 11-3-1969, 11-4-1969, 11-5-1969, 11-6-1969, 11-7-1969, 11-8-1969, 11-9-1969, 11-10-1969, 11-11-1969, 11-12-1969, 11-13-1969, 11-14-1969, 11-15-1969, 11-1*

SUMMARY

15. In the past, in the United States, we have been known for our freedom of expression, but we have not always been known for our freedom of information. The purpose of this report is to provide a summary of the information that is available to the public.

"Staple" is used to designate a group of chapter elements which are usually twisted together to form a long, continuous thread.

Non-absorbable surgically acceptable filaments include
25 filaments of polyalkylenes, such as polyethylene, preferably
linear polyethylene with a density of about 0.94
or higher; or polypropylene, preferably a linear polypropylene;
or a polyamide, such as nylon; or a polyester,
such as Dacron; or a polyacrylamide, such as Colla or
30 Creston; or a halogenated polyalkylene, such as poly-
tetrafluoroethylene, such as Teflon, or other halogenated
polyalkylene, such as Kel-F or FEP; or carbon, or silk,
or linen; or a metal such as stainless steel, titanium,
silver, gold, or platinum. The above are all suitable. Any
45 non-absorbable material which is essentially inert in living
mammalian tissue, particularly human tissue, is usable as
a non-absorbable filament. Those materials having a com-
paratively high tensile strength and flexibility are preferred.

10 An absorbable filament is one which is absorbable, that is, digested or dissolved, in living mammalian tissue.

A "thread" is a plurality of filaments, either continuous or staple, twisted together.

45 A braid is a plurality of strands or threads twisted, plaited, braided, or laid parallel to form a cord for further construction into a fabric, or used per se, or a monofilament of such size as to be woven or used independently.

50 A "bi-component filament" is a filament composed of two separate materials. As used herein, the term is limited to a filament having one non-absorbable component and

one absorbable component. The components may be adjacent. The most easily formed and referred to component filament is a sheath filament with an internal non-absorbable material coated, or sheathed, portion around its length with an absorbable component.

"A three-component thread" includes a thread of three component filaments or a blend of different separate monofilaments.

60 A "bicomponent strand" is a strand of one or more bicomponent filaments, or two different filament materials or both, at least one component of which is absorbable.

A "two-component fabric" is a woven, knitted, or otherwise formed fabric of at least two dimensions or fabric units having separate strands of two component materials or strands of two components, or of two component materials having different characteristics.

A "coated fabric" is a fabric which is covered with a thin, usually continuous sheet of material. For example, by far the most common example is a fabric system of water-repellent material, such as that found in the manufacture of raincoats.

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C.A. No.04-12457 PBS
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polymerization of glycolide, the polymerization of glycolide is initiated by a catalyst.

PGAs are also used in a variety of other applications. For example, they have been used as a coating for sutures. The coating is applied to the suture by dipping the suture in a solution of the polymer. The coating is then dried, leaving a thin layer of polymer on the suture. This coating helps to prevent the suture from being absorbed by the body. PGAs are also used in the form of fibers. These fibers are used in a variety of applications, including as a reinforcement for prostheses and as a component of tissue engineering scaffolds.

A "gradual transition section" is a portion of biocompatible fabric or fiber component, in which a collection of strands for the fabric or components for the strand or strands, having a living component, over a short distance, of 1 mm. to 15 mm. or more, so that a firm or strand changes in its composition from nonabsorbable material, or substantially nonabsorbable material, to predominantly or completely absorbable material, whereby living tissue can replace the absorbable component and a gradual transition is accomplished between the nonabsorbable reinforcing prosthesis and the adjacent living tissue. With an arterial implant, for instance, a portion of the vessel has been the line of junction between the implant and the arterial artery wall. With a gradual transition, no sharp line of demarcation exists, and, hence, failures between the prosthesis and tissue are minimized. With implants of the types shown by Usher, supra, the edges of the reinforcing element could cause difficulties. With a gradual transition, a line of potential risk is eliminated.

For different purposes and in different types of tissue the rate of absorption may vary but in general an absorbable prosthesis should have a high portion of its original strength as possible for at least three days, and sometimes as much as fifteen days or more, and preferably should be completely absorbed by muscular tissue within from forty-five to ninety days or more depending on the mass of the cross-section. The rate of absorption in other tissues may vary even more.

In coming with many biological systems, the requirements are not absolute and the rate of absorption as well as the short-term strength requirement varies from patient to patient and at different locations within the body, as well as with the thickness of the section of PGA.

The PGA may be formed as tubes or sheets for surgical repair and may also be spun as thin filaments and woven or felted to form absorbable sponges or absorbable gauze, or used in combination with other structures as prosthetic devices, within the body of a human or animal where it is desirable that the structure have short-term strength, but be absorbable. The useful end applications include tubes, including branched tubes or T's, for artery, vein or intestinal repair, nerve sheaths, tendon splints, sheets for lining up and supporting damaged tissues, liver and other intestinal organs, protecting damaged surface areas such as abrasions, partial burns, sprains, or areas where the skin and underlying tissues are damaged or surgically removed.

The synthetic character and hence predictable formability and properties of the polymer are obtainable from a controlled process, thereby providing

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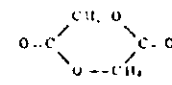
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the cyclic dimeric condensation product formed by dehydrating hydroxyacetic acid. During polymerization of glycolide, the ring is broken and straight-chain polymerization occurs.

Small quantities of other materials may be present in the chain, as for example, deltamethrin acid, its especially active forms, homologs, and analogs. In general, plasticizers tend to interfere with crystallinity, orientation, etc. and weaken fibers, but are useful for sponges and films. Other substances may be present, such as dyes, antibiotics, antiseptics, anesthetics, and antioxidants. The surfaces of the fabric can be coated with a silicone, brom wax, and the like to modify the handling or absorption rate.

The polymerization of glycolide occurs by heating with or without a catalyst, or may be induced by radiation such as X-rays, gamma rays, electron beams, etc. Polymers may also be obtained by condensing glycolic acid or chloroacetic acid with or without a catalyst under a variety of conditions. Good moldable objects or films are most readily obtained when the melt viscosity at 245° C. is about 400 to about 27,000 poises.

Polyhydroxyacetic esters have been described in United States Patent 2,068,162, Loae, "Preparation of High Molecular Weight Polyhydroxyacetic Ester," and United States Patent 2,676,315, Higgins, "Condensation Polymer of Hydroxyacetic Acid."

The processes described in the above 143 patent can be used for producing PGA from which prostheses may be made. Additives such as triphenyl phosphite or S-nitro-Nov, a disulfide aromatic phenol, can be added as color stabilizers.

DRAWINGS

FIGURE 1 shows a cross-section of a polymeric material having a thickness of about 0.1 mm. and a width of about 1 mm. The material is coated with a thin layer of a biocompatible material.

FIGURE 2 shows a cross-section of a polymeric material having a thickness of about 0.1 mm. and a width of about 1 mm. The material is coated with a thin layer of a biocompatible material.

FIGURE 3 shows a cross-section of a polymeric material having a thickness of about 0.1 mm. and a width of about 1 mm. The material is coated with a thin layer of a biocompatible material.

the 1990s, the number of people in the United States who are 65 years of age or older has increased by 50% (U.S. Census Bureau, 2000). The number of people aged 65 and older is projected to increase to 20% of the total population by the year 2020 (U.S. Census Bureau, 2000). The increase in the number of people aged 65 and older is expected to be the largest increase in the population of any age group in the United States (U.S. Census Bureau, 2000). The increase in the number of people aged 65 and older is expected to be the largest increase in the population of any age group in the United States (U.S. Census Bureau, 2000).

1. *Phylogenetic relationships*—The phylogenetic relationships of the 12 species were determined using the parsimony method. The characters were ordered by the method of Bremer (1994) and the tree was constructed using the program PAUP (version 4.0) (Nelson & OlSEN, 1992). The tree was rooted with *Phyllanthus* as the outgroup. The characters were ordered by the method of Bremer (1994) and the tree was constructed using the program PAUP (version 4.0) (Nelson & OlSEN, 1992). The tree was rooted with *Phyllanthus* as the outgroup.

[illegible]

116. U.S. Fish and Wildlife Service, *Wildlife Conservation*, 1971, p. 130.

those with a high degree of confidence in the results.

1160011. H. *in* a cross section of septal an an internal sleeve; with expanded cells.

FIGURE 12. Shows a portion of the sleeve forming after coupling of solid polyethylene lined with bonding ends to old in holding a fixed vertical sleeve.

FIGURE 13 shows the sleeve of FIGURE 12 which an external spring clip of solid polyethylene holds the ends of the blood vessel to restrain.

FIGURE 14 shows the slices of FIGURE 13, two expandable annular clips are used to fix the blood vessel approximated.

FIGURE 15 is a portion of a woven tube individual strands which are at least in part

FIGURE 16 shows a portion of a heart valve in heart tissue using a fabric in part composed of polyacetic acid to aid in holding the valve in place.

FIGURE 17 shows a broken bone, the ends are held together by a solid bar of polyglycol held to the bone by polyglycolic acid screws.

FIGURE 18 shows a broken tube, the ends are held in position by an internal fitted polyethylene acid.

the drawings can be produced as set forth in the examples, in which parts are by weight, unless clearly indicated:

EXAMPLE 1

100 parts of recrystallized glycolide (m.p. 83.0 to 85.5° C.) are intimately mixed with methoxyacetic acid, 0.03 part of phosbolol (Nax), and 0.01 part antimony triiodide. Spindles are each charged with approximately 25 g. of the mixture, deoxygenated by repeated vacuum purging, then sealed under vacuum and heated to 185 to 190° C. for 48 hours. On cooling a waxy tough PGA is produced in a 97.5% yield having a viscosity at 245° C. of 5,000 poises. The polymer is heated and spun into filaments at a temperature of 230° C. at a speed of about 150 feet per minute. Filaments produced are cooled, then drawn at a 10:1 ratio. When drawn to five times the original length, tough filament is produced. The dry filament is ready for use.

EXAMPLE 2

The polymer of the preceding example is a plurality of smaller elements, each of which is twisted into a polydimenitonal strand, which are twisted following the technique of Example

Because it is a synthetic polymer, the following are more versatile than in staining of natural materials.

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the 1990s, the use of the term "cognitive" has been associated with a new emphasis on the role of the individual in the learning process. This emphasis has been reflected in the development of a variety of instructional strategies that are designed to promote active learning and the development of higher-order thinking skills. One of the most prominent of these strategies is the use of problem-based learning (PBL), which involves presenting students with a complex problem and allowing them to work together to develop a solution. PBL is based on the idea that students learn best when they are actively engaged in the learning process and when they are able to apply their knowledge to a real-world problem. Another instructional strategy that has gained popularity in the 1990s is the use of collaborative learning, which involves students working together in small groups to complete a task or solve a problem. Collaborative learning is based on the idea that students learn best when they are able to learn from each other and when they are able to share their knowledge and experiences. The use of these instructional strategies has led to a number of positive outcomes, including improved student motivation, increased student participation in the learning process, and improved student learning outcomes. However, there are also some challenges associated with the use of these strategies, such as the need for careful planning and monitoring, and the need for students to have a strong foundation of knowledge and skills. Despite these challenges, the use of these instructional strategies is likely to continue to be a key component of effective instruction in the 21st century.

The Fe^{3+} ions were precipitated as $\text{Fe}(\text{OH})_3$ in the presence of NaOH and the $\text{Fe}(\text{OH})_3$ was dried at 100°C for 24 h and calcined at 500°C for 2 h. The Fe_2O_3 was obtained by calcining the $\text{Fe}(\text{OH})_3$ at 500°C for 2 h.

[illegible]

of 1.00, 2.00 and 3.00, respectively, based on the weight of the substantially pure polymer component, and 0.5 part of butyl alcohol, which is substantially pure, based on the weight of the

steel 8.14 mm diameter, the tube is extended and pulled by a spring. The tube is extended back to a posi-

53. The top of the cone is a circle of radius r and the top is vertical. The cone is to be placed in a vertical position in a closed

reactant is prepared in a vessel packed in a closed glass chamber throughout which dimethyl phthalate is refluxed at 222° C. The heating part of the dimethyl phthalate is controlled by decreasing the pressure of the

40 plate state is controlled by controlling the pressure of the system. At periodic intervals after melting, the viscosity of the reaction mixture is measured by raising the steel ball by a piston from the bottom and measuring the rate of the

at 2200 gauss, indicating 100 min. as the ball drop time.

The FGA thus produced is spun into .002 inch diameter fibers and used for a base component strands.

50 Dacron® filaments, in varying weight ratios to form bi-component strands which are braided into tubular artificial arteries to confer the necessary elasticity.

Additional PGA, similarly produced, is used to form sheets. These sheets are wrapped around nerves, traumatically severed, to protect such nerves from invasive scar tissue growth while the nerve is regenerating.

Also the PGA so produced is fabricated into the prosthetic devices shown in the drawings.

(c) 23 was formed by dipping a non-absorbable filament 21 of Dacron into a PG A-melt forming a PGA coating 22 on the surface of the non-absorbable Dacron 21.

As seen in FIGURE 1 the dip was such that approximately 25% of the cross section was of Ducon and 75% of PGL.

In FIGURE 2 the structure is the same except that the relative proportions are changed to approximately 50% of each material.

For preparations of 1 and 3 the structure is the same except that the proportions are changed such that approximately 75% of the ester is in the *trans* form and about 25% in the *cis* form (Table 1).

1. The value of β is shown.

75. 1991-1992, 1992-1993, 1993-1994, 1994-1995, 1995-1996, 1996-1997, 1997-1998, 1998-1999, 1999-2000, 2000-2001, 2001-2002, 2002-2003, 2003-2004, 2004-2005, 2005-2006, 2006-2007, 2007-2008, 2008-2009, 2009-2010, 2010-2011, 2011-2012, 2012-2013, 2013-2014, 2014-2015, 2015-2016, 2016-2017, 2017-2018, 2018-2019, 2019-2020, 2020-2021, 2021-2022, 2022-2023, 2023-2024, 2024-2025, 2025-2026, 2026-2027, 2027-2028, 2028-2029, 2029-2030, 2030-2031, 2031-2032, 2032-2033, 2033-2034, 2034-2035, 2035-2036, 2036-2037, 2037-2038, 2038-2039, 2039-2040, 2040-2041, 2041-2042, 2042-2043, 2043-2044, 2044-2045, 2045-2046, 2046-2047, 2047-2048, 2048-2049, 2049-2050, 2050-2051, 2051-2052, 2052-2053, 2053-2054, 2054-2055, 2055-2056, 2056-2057, 2057-2058, 2058-2059, 2059-2060, 2060-2061, 2061-2062, 2062-2063, 2063-2064, 2064-2065, 2065-2066, 2066-2067, 2067-2068, 2068-2069, 2069-2070, 2070-2071, 2071-2072, 2072-2073, 2073-2074, 2074-2075, 2075-2076, 2076-2077, 2077-2078, 2078-2079, 2079-2080, 2080-2081, 2081-2082, 2082-2083, 2083-2084, 2084-2085, 2085-2086, 2086-2087, 2087-2088, 2088-2089, 2089-2090, 2090-2091, 2091-2092, 2092-2093, 2093-2094, 2094-2095, 2095-2096, 2096-2097, 2097-2098, 2098-2099, 2099-2100, 2100-2101, 2101-2102, 2102-2103, 2103-2104, 2104-2105, 2105-2106, 2106-2107, 2107-2108, 2108-2109, 2109-2110, 2110-2111, 2111-2112, 2112-2113, 2113-2114, 2114-2115, 2115-2116, 2116-2117, 2117-2118, 2118-2119, 2119-2120, 2120-2121, 2121-2122, 2122-2123, 2123-2124, 2124-2125, 2125-2126, 2126-2127, 2127-2128, 2128-2129, 2129-2130, 2130-2131, 2131-2132, 2132-2133, 2133-2134, 2134-2135, 2135-2136, 2136-2137, 2137-2138, 2138-2139, 2139-2140, 2140-2141, 2141-2142, 2142-2143, 2143-2144, 2144-2145, 2145-2146, 2146-2147, 2147-2148, 2148-2149, 2149-2150, 2150-2151, 2151-2152, 2152-2153, 2153-2154, 2154-2155, 2155-2156, 2156-2157, 2157-2158, 2158-2159, 2159-2160, 2160-2161, 2161-2162, 2162-2163, 2163-2164, 2164-2165, 2165-2166, 2166-2167, 2167-2168, 2168-2169, 2169-2170, 2170-2171, 2171-2172, 2172-2173, 2173-2174, 2174-2175, 2175-2176, 2176-2177, 2177-2178, 2178-2179, 2179-2180, 2180-2181, 2181-2182, 2182-2183, 2183-2184, 2184-2185, 2185-2186, 2186-2187, 2187-2188, 2188-2189, 2189-2190, 2190-2191, 2191-2192, 2192-2193, 2193-2194, 2194-2195, 2195-2196, 2196-2197, 2197-2198, 2198-2199, 2199-2200, 2200-2201, 2201-2202, 2202-2203, 2203-2204, 2204-2205, 2205-2206, 2206-2207, 2207-2208, 2208-2209, 2209-2210, 2210-2211, 2211-2212, 2212-2213, 2213-2214, 2214-2215, 2215-2216, 2216-2217, 2217-2218, 2218-2219, 2219-2220, 2220-2221, 2221-2222, 2222-2223, 2223-2224, 2224-2225, 2225-2226, 2226-2227, 2227-2228, 2228-2229, 2229-2230, 2230-2231, 2231-2232, 2232-2233, 2233-2234, 2234-2235, 2235-2236, 2236-2237, 2237-2238, 2238-2239, 2239-2240, 2240-2241, 2241-2242, 2242-2243, 2243-2244, 2244-2245, 2245-2246, 2246-2247, 2247-2248, 2248-2249, 2249-2250, 2250-2251, 2251-2252, 2252-2253, 2253-2254, 2254-2255, 2255-2256, 2256-2257, 2257-2258, 2258-2259, 2259-2260, 2260-2261, 2261-2262, 2262-2263, 2263-2264, 2264-2265, 2265-2266, 2266-2267, 2267-2268, 2268-2269, 2269-2270, 2270-2271, 2271-2272, 2272-2273, 2273-2274, 2274-2275, 2275-2276, 2276-2277, 2277-2278, 2278-2279, 2279-2280, 2280-2281, 2281-2282, 2282-2283, 2283-2284, 2284-2285, 2285-2286, 2286-2287, 2287-2288, 2288-2289, 2289-2290, 2290-2291, 2291-2292, 2292-2293, 2293-2294, 2294-2295, 2295-2296, 2296-2297, 2297-2298, 2298-2299, 2299-2300, 2300-2301, 2301-2302, 2302-2303, 2303-2304, 2304-2305, 2305-2306, 2306-2307, 2307-2308, 2308-2309, 2309-2310, 2310-2311, 2311-2312, 2312-2313, 2313-2314, 2314-2315, 2315-2316, 2316-2317, 2317-2318, 2318-2319, 2319-2320, 2320-2321, 2321-2322, 2322-2323, 2323-2324, 2324-2325, 2325-2326, 2326-2327, 2327-2328, 2328-2329, 2329-2330, 2330-2331, 2331-2332, 2332-2333, 2333-2334, 2334-2335, 2335-2336, 2336-2337, 2337-2338, 2338-2339, 2339-2340, 2340-2341, 2341-2342, 2342-2343, 2343-2344, 2344-2345, 2345-2346, 2346-2347, 2347-2348, 2348-2349, 2349-2350, 2350-2351, 2351-2352, 2352-2353, 2353-2354, 2354-2355, 2355-2356, 2356-2357, 2357-2358, 2358-2359, 2359-2360, 2360-2361, 2361-2362, 2362-2363

1. 2. 3. 4. 5. 6. 7. 8. 9. 10. 11. 12. 13. 14. 15. 16. 17. 18. 19. 20. 21. 22. 23. 24. 25. 26. 27. 28. 29. 30. 31. 32. 33. 34. 35. 36. 37. 38. 39. 40. 41. 42. 43. 44. 45. 46. 47. 48. 49. 50. 51. 52. 53. 54. 55. 56. 57. 58. 59. 60. 61. 62. 63. 64. 65. 66. 67. 68. 69. 70. 71. 72. 73. 74. 75. 76. 77. 78. 79. 80. 81. 82. 83. 84. 85. 86. 87. 88. 89. 90. 91. 92. 93. 94. 95. 96. 97. 98. 99. 100. 101. 102. 103. 104. 105. 106. 107. 108. 109. 110. 111. 112. 113. 114. 115. 116. 117. 118. 119. 120. 121. 122. 123. 124. 125. 126. 127. 128. 129. 130. 131. 132. 133. 134. 135. 136. 137. 138. 139. 140. 141. 142. 143. 144. 145. 146. 147. 148. 149. 150. 151. 152. 153. 154. 155. 156. 157. 158. 159. 160. 161. 162. 163. 164. 165. 166. 167. 168. 169. 170. 171. 172. 173. 174. 175. 176. 177. 178. 179. 180. 181. 182. 183. 184. 185. 186. 187. 188. 189. 190. 191. 192. 193. 194. 195. 196. 197. 198. 199. 200. 201. 202. 203. 204. 205. 206. 207. 208. 209. 210. 211. 212. 213. 214. 215. 216. 217. 218. 219. 220. 221. 222. 223. 224. 225. 226. 227. 228. 229. 230. 231. 232. 233. 234. 235. 236. 237. 238. 239. 240. 241. 242. 243. 244. 245. 246. 247. 248. 249. 250. 251. 252. 253. 254. 255. 256. 257. 258. 259. 260. 261. 262. 263. 264. 265. 266. 267. 268. 269. 270. 271. 272. 273. 274. 275. 276. 277. 278. 279. 280. 281. 282. 283. 284. 285. 286. 287. 288. 289. 290. 291. 292. 293. 294. 295. 296. 297. 298. 299. 300. 301. 302. 303. 304. 305. 306. 307. 308. 309. 310. 311. 312. 313. 314. 315. 316. 317. 318. 319. 320. 321. 322. 323. 324. 325. 326. 327. 328. 329. 330. 331. 332. 333. 334. 335. 336. 337. 338. 339. 340. 341. 342. 343. 344. 345. 346. 347. 348. 349. 350. 351. 352. 353. 354. 355. 356. 357. 358. 359. 360. 361. 362. 363. 364. 365. 366. 367. 368. 369. 370. 371. 372. 373. 374. 375. 376. 377. 378. 379. 380. 381. 382. 383. 384. 385. 386. 387. 388. 389. 390. 391. 392. 393. 394. 395. 396. 397. 398. 399. 400. 401. 402. 403. 404. 405. 406. 407. 408. 409. 410. 411. 412. 413. 414. 415. 416. 417. 418. 419. 420. 421. 422. 423. 424. 425. 426. 427. 428. 429. 430. 431. 432. 433. 434. 435. 436. 437. 438. 439. 440. 441. 442. 443. 444. 445. 446. 447. 448. 449. 450. 451. 452. 453. 454. 455. 456. 457. 458. 459. 460. 461. 462. 463. 464. 465. 466. 467. 468. 469. 470. 471. 472. 473. 474. 475. 476. 477. 478. 479. 480. 481. 482. 483. 484. 485. 486. 487. 488. 489. 490. 491. 492. 493. 494. 495. 496. 497. 498. 499. 500. 501. 502. 503. 504. 505. 506. 507. 508. 509. 510. 511. 512. 513. 514. 515. 516. 517. 518. 519. 520. 521. 522. 523. 524. 525. 526. 527. 528. 529. 530. 531. 532. 533. 534. 535. 536. 537. 538. 539. 540. 541. 542. 543. 544. 545. 546. 547. 548. 549. 550. 551. 552. 553. 554. 555. 556. 557. 558. 559. 560. 561. 562. 563. 564. 565. 566. 567. 568. 569. 570. 571. 572. 573. 574. 575. 576. 577. 578. 579. 580. 581. 582. 583. 584. 585. 586. 587. 588. 589. 590. 591. 592. 593. 594. 595. 596. 597. 598. 599. 600. 601. 602. 603. 604. 605. 606. 607. 608. 609. 610. 611. 612. 613. 614. 615. 616. 617. 618. 619. 620. 621. 622. 623. 624. 625. 626. 627. 628. 629. 630. 631. 632. 633. 634. 635. 636. 637. 638. 639. 640. 641. 642. 643. 644. 645. 646. 647. 648. 649. 650. 651. 652. 653. 654. 655. 656. 657. 658. 659. 660. 661. 662. 663. 664. 665. 666. 667. 668. 669. 670. 671. 672. 673. 674. 675. 676. 677. 678. 679. 680. 681. 682. 683. 684. 685. 686. 687. 688. 689. 690. 691. 692. 693. 694. 695. 696. 697. 698. 699. 700. 701. 702. 703. 704. 705. 706. 707. 708. 709. 710. 711. 712. 713. 714. 715. 716. 717. 718. 719. 720. 721. 722. 723. 724. 725. 726. 727. 728. 729. 730. 731. 732. 733. 734. 735. 736. 737. 738. 739. 740. 741. 742. 743. 744. 745. 746. 747. 748. 749. 750. 751. 752. 753. 754. 755. 756. 757. 758. 759. 760. 761. 762. 763. 764. 765. 766. 767. 768. 769. 770. 771. 772. 773. 774. 775. 776. 777. 778. 779. 780. 781. 782. 783. 784. 785. 786. 787. 788. 789. 790. 791. 792. 793. 794. 795. 796. 797. 798. 799. 800. 801. 802. 803. 804. 805. 806. 807. 808. 809. 810. 811. 812. 813. 814. 815. 816. 817. 818. 819. 820. 821. 822. 823. 824. 825. 826. 827. 828. 829. 830. 831. 832. 833. 834. 835. 836. 837. 838. 839. 840.

It is to be understood that in the event of a change in the name of the company, the name of the company shall be changed to the name of the company as it appears on the face of the certificate of incorporation of the company, and the name of the company shall be changed to the name of the company as it appears on the face of the certificate of incorporation of the company.

1971-87). Soils in watersheds with a forest cover of 10% or more were of 1-2% water content, whereas those with a forest cover of 10% or less were of 13-15% water content, with an 18% increase in the latter (33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55) and a change by 25% in the former (33, 34, 35) and the latter (33, 34, 35) until the watershed of 10-20% forest cover was 35% non-soluble and 75% TGA.

Such a configuration permits the use of a woven or knitted polyethylene or isotactic polypropylene in the construction of a repair patch, such as shown in Figure 1, in which protrusions from the fabric reinforcement, preferably suitably inert material, through the mesh of the patch, to the spacing between the threads in the fabric, can be chosen for a particular application. Usage of the prosthetic device is to be used for the repair of a lumen, a comparatively widely spaced weave is desired. If used for an area in which fluid retention is critical, such as an artery or vein, the weave is much closer.

In FIGURE 9 is shown a knitted fabric 27, in which the respective strands are 100% non-absorbable 21, followed by two rows of 75% non-absorbable 21, 25% PGA 29, followed by two rows of 50% non-absorbable 21, 50% PGA 29, followed by two rows of 25% non-absorbable 21, 75% PGA 29, followed by two rows of 25% non-absorbable 21, 75% PGA 31.

PGA 31. In such a graded construction, the rate of change with distance or the number of rows of a particular composition are adjusted to fit the desired use. For smaller patches the width of each proportion of components is smaller than for large patches.

In FIGURE 10 is shown an artery 37 which is joined together on a tapered end PGA tube 34 which forms a stent about which the ends of the tube are well secured by a suture splice 39. The tapered end is easier to insert in the artery.

In FIGURE 11 the artery walls 40 are joined together over a cannula and PGA tube 41 and the ends are joined by a suture splice 42.

FIGURE 12 shows the flared end PGA tube 41. In FIGURE 13 is shown a blood vessel 43, the ends of which are each separately placed over the end of a flared PGA tube and which blood vessel is held in place of the end adjacent to permit healing by a PGA spring clip 44. FIG. 14, as produced in the above Example 3, shows an end having a strength of 0.14 to 0.18 per inch width or greater. It may be bent and formed into a desired shape which shape is returned on cooling, and by shaping as a flat spring clip, can be used to hold together the walls of a blood vessel 43 until a natural scar tissue has taken place.

FIGURE 13 is shown in the sphere of a blood vessel 45 but in which the end is tied together by an annular clip 46 of a different size. Such end clips are well known for the purpose of tied end lines to indicators in a method of measuring the rate of fluid flow due to a connection between the shape of fluidator and shape, as is well known in the art, the total compression at the point of connection may be caused to be appreciable and the rate of flow varied in time. This is important in the case of blood vessels and a

[illegible]

1. The first step in the process is to identify the problem. This involves gathering information about the situation and the people involved. It is important to understand the context and the stakes of the problem.

[illegible]

Also, visible spikes or bone pins hold the bone in place until it has an opportunity to knit and form a healthy ligament. In the past, available reinforcing elements have, frequently been a real bummer. The elements add weight to the body, and the pins cause inflammation by the physical pressure. It must be removed at a separate subsequent operation. If, ideally, if a bone pin is substantially of a bone, the volume of bone marrow is inevitably reduced. When the body bone pin dissolves, no scar tissue remains and bone marrow is regenerated through the bone pores—the bone marrow to accomplish its original functions.

The drawings above are illustrative only, or environment of the present invention in which various prosthetic devices are incorporated into the human body to aid impaired functions of natural elements. From the above drawings and descriptions, it will be obvious to those skilled in the art that many other modifications may be adapted for particular injuries or ills to which the flesh is heir.

The finding that polyglycolic acid, abbreviated PGA, is absorbable in living tissue, and has marked mechanical strength, as a fiber or solid, including suture, and hence can be used as an element in, or as, a surgical prosthesis, is most unexpected and unpredictable.

Calcium, or regenerated collagen has in the past been used for tissue replacement, but with collagen, as the collagen is absorbed, a fibrotic tract replaces the collagen, so that in effect scar tissue remains at the site of the implanted collagen for many years, in many instances for life. Some patients are allergic to collagen. PGA is not a protein, has no amino acids, and has given no evidence of allergic reactions in thousands of implants. With the present PGA prostheses, the PGA is completely absorbed, and a minimal or no trace of the inserted matter remains after a comparatively short period. This complete absorption, without residual fibrotic tissue, is unique, and an important consideration to surgery.

As it is obvious that extrapolation of such prostatic densities in humans must wait until autopsy, after which the actual curves, experimental results were conducted on laboratory animals which would permit accurate and extrapolation of the limited periods. These are shown in the following examples:

EXAMPLE 4

Atrophic intercalary rod

4. Several initiatives were made on the subject with the following objectives: to bring the subject to the attention of one of the national radio stations to cause the

the bone. The bone was then removed and the implant was placed in a container of 10% formalin solution. The bone was then removed and the implant was placed in a container of 10% formalin solution. The bone was then removed and the implant was placed in a container of 10% formalin solution.

The implant was then removed and the bone was placed in a container of 10% formalin solution. The bone was then removed and the implant was placed in a container of 10% formalin solution. The bone was then removed and the implant was placed in a container of 10% formalin solution.

With both the experimental and control animals the course of healing was unremarkable. The bone was essentially healed by the fourth week. After seven weeks the femurs were cut longitudinally and the effect of time on the implants was observed. As expected in the relatively short time used the stainless steel pin was completely intact but since the internal space was largely occupied where the metal pin was present, there was no marrow tissue.

Where the medullary rod of polyglycolic acid had been used, at six weeks the overall structure of the rod was essentially unchanged but there were fissures developing on the surface and the cut ends which had been sharply defined were somewhat rounded. The rod was somewhat softened on the surface. There was a progressive increase in the amount of erosion of the PGA rod and at the end but this erosion was rather associated with inflammation or other adverse reaction. By the 24th week the rod of polyglycolic acid was essentially digested and the bone now showed normal tissue architecture.

EXAMPLE 5

A stable bone plate affixed with absorbable pins

Femurs of the hind legs of rabbits were fractured as described in Example 4. The cut ends were reapproximated and immobilized by use of an internal support made from a sheet of polyglycolic acid approximately 1/2 inch thick 1/4 inch wide and 1 inch long, shaped to conform generally to the bone by softening the plastic with heat and pre-molding it about a metal rod of suitable diameter. The premolded plate was centrally located over the cut bone and while held in position, small holes were drilled through the plate and completely through the bone with a 1/16 inch drill, two holes on each side of the bone break. Small PGA nails about 1/16 inch long and slightly over 1/16 inch in diameter made by heating rod of this diameter by pressing against a heated surface were driven through the holes in the PGA plate and completely through the bone to hold the plate in place. The soft tissue was reapproximated, the incision ligatures tied and the animals were returned to their cages. X-rays were taken weekly and animals were sacrificed at 3, 6, 12, 18 and 24 week intervals. The leg which had been operated on were carefully dissected to determine the fate of the soft tissue and implant and to observe the course of healing. At 3 weeks the bone was completely healed. The PGA implant was essentially intact. By 6 weeks the bone had healed and the PGA plate was completely digested. The bone was then removed and the implant was placed in a container of 10% formalin solution.

At 12 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 18 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 24 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 30 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 36 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 42 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 48 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 54 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 60 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 66 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 72 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 78 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 84 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 90 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 96 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 102 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 108 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 114 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 120 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 126 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 132 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 138 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 144 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 150 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 156 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 162 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 168 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 174 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 180 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 186 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 192 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 198 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 204 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

At 210 weeks the bone was completely healed and the implant was placed in a container of 10% formalin solution.

[illegible]

2007-2008 C&D

UNIQUE SELLING POINTS

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|-----------|------------|-----------|------------|---------|
| 3,272,734 | 3,149,676 | 3,272,734 | 3,149,676 | 128-334 |
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| 3,272,734 | 1,149,676 | 3,272,734 | 1,149,676 | 128-334 |
| 3,272,734 | 2,149,676 | 3,272,734 | 2,149,676 | 128-334 |
| 3,272,734 | 3,149,676 | 3,272,734 | 3,149,676 | 128-334 |
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| 3,272,734 | 14,149,676 | 3,272,734 | 14,149,676 | 128-334 |
| 3,272,734 | 15,149,676 | 3,272,734 | 15,149,676 | 128-334 |
| 3,272,734 | 16,149,676 | 3,272,734 | 16,149,676 | 128-334 |
| 3,272,734 | 17,149,676 | 3,272,734 | 17,149,676 | 128-334 |
| 3,272,734 | 18,149,676 | 3,272,734 | 18,149,676 | 128-334 |
| 3,272,734 | 19,149,676 | 3,272,734 | 19,149,676 | 128-334 |
| 3,272,734 | 20,149,676 | 3,272,734 | 20,149,676 | 128-334 |
| 3,272,734 | 21,149,676 | 3,272,734 | 21,149,676 | 128-334 |
| 3,272,734 | 22,149,676 | 3,272,734 | 22,149,676 | 128-334 |
| 3,272,734 | 23,149,676 | 3,272,734 | 23,149,676 | 128-334 |
| 3,272,734 | 24,149,676 | 3,272,734 | 24,149,676 | 128-334 |
| 3,272,734 | 25,149,676 | 3,272,734 | 25,149,676 | 128-334 |
| 3,272,734 | 26,149,676 | 3,272,734 | 26,149,676 | 128-334 |
| 3,272,734 | 27,149,676 | 3,272,734 | 27,149,676 | 128-334 |
| 3,272,734 | 28,149,676 | 3,272,734 | 28,149,676 | 128-334 |
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| 3,272,734 | 31,149,676 | 3,272,734 | 31,149,676 | 128-334 |
| 3,272,734 | 32,149,676 | 3,272,734 | 32,149,676 | 128-334 |
| 3,272,734 | 33,149,676 | 3,272,734 | 33,149,676 | 128-334 |
| 3,272,734 | 34,149,676 | 3,272,734 | 34,149,676 | 128-334 |
| 3,272,734 | 35,149,676 | 3,272,734 | 35,149,676 | 128-334 |
| 3,272,734 | 36,149,676 | 3,272,734 | 36,149,676 | 128-334 |
| 3,272,734 | 37,149,676 | 3,272,734 | 37,149,676 | 128-334 |
| 3,272,734 | 38,149,676 | 3,272,734 | 38,149,676 | 128-334 |
| 3,272,734 | 39,149,676 | 3,272,734 | 39,149,676 | 128-334 |
| 3,272,734 | 40,149,676 | 3,272,734 | 40,149,676 | 128-334 |
| 3,272,734 | 41,149,676 | 3,272,734 | 41,149,676 | 128-334 |
| 3,272,734 | 42,149,676 | 3,272,734 | 42,149,676 | 128-334 |
| 3,272,734 | 43,149,676 | 3,272,734 | 43,149,676 | 128-334 |
| 3,272,734 | 44,149,676 | 3,272,734 | 44,149,676 | 128-334 |
| 3,272,734 | 45,149,676 | 3,272,734 | 45,149,676 | 128-334 |
| 3,272,734 | 46,149,676 | 3,272,734 | 46,149,676 | 128-334 |
| 3,272,734 | 47,149,676 | 3,272,734 | 47,149,676 | 128-334 |
| 3,272,734 | 48,149,676 | 3,272,734 | 48,149,676 | 128-334 |
| 3,272 | | | | |

U.S. CL. X.R.

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[15] 3,636,956

[45] Jan. 25, 1972

Schneider

[54] POLYLACTIDE SUTURES

[72] Inventor Allan K. Schneider, Wilmington, Del.

[73] Assignee Ethicon, Inc., Somerville, N.J.

[22] Filed May 13, 1970

[21] Appl. No. 36,797

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 700,036, Jan. 24, 1968, abandoned, which is a continuation-in-part of Ser. No. 449,630, Apr. 20, 1965, abandoned, which is a continuation-in-part of Ser. No. 308,688, Sept. 13, 1963, abandoned, which is a continuation-in-part of Ser. No. 231,860, Oct. 19, 1962, abandoned

[52] U.S. Cl. 128/335.5; 260/78.3

[51] Int. Cl. A61B 17/00

[58] Field of Search 128/334, 335.5; 260/78.3

[56] References Cited

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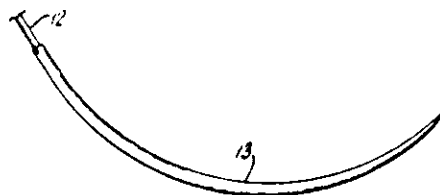
Primary Examiner—Dalton L. Truluck

Attorney—Robert W. Kell and Robert L. Miner

[57] ABSTRACT

Absorbable surgical sutures that are dimensionally stable within the body may be prepared by the extrusion of polylactide polymer, including copolymers of L(-) lactide with up to 35 mole percent of glycolide. Said polymers are characterized by an inherent viscosity of at least 1.0, and the extruded filaments are oriented by drawing at a temperature of about 50° to about 140° at a draw ratio of up to 11:1, and annealed. Sutures so prepared have a tensile strength of from 25,000 p.s.i. to 100,000 p.s.i.

79 Claims, 5 Drawing Figures



PATENTED JAN 25 1972

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FIG. 1.

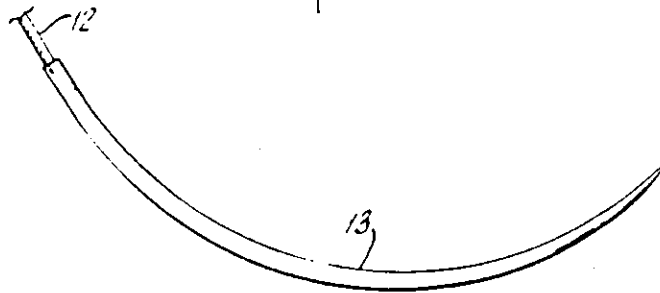


FIG. 2.

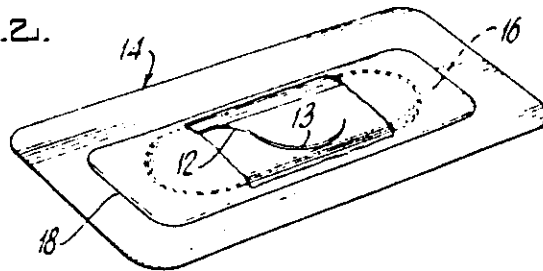


FIG. 3.

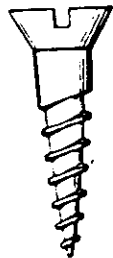


FIG. 4.

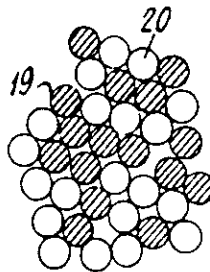
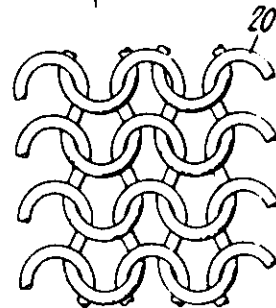


FIG. 5.



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ATTORNEY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI000286

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TABLE I

| | Tensile strength (straight pull) p.s.i. | Percent elongation at break | Tensile strength (surgeon's knot) p.s.i. | Percent loss in strength, knot vs. straight |
|---|---|-----------------------------|--|---|
| Poly-L(-) lactide | 115,000 | 17 | 83,000 | 29 |
| Do | 105,000 | 16 | 78,000 | 26 |
| Catgut | 50,000 | 20 | 29,000 | 42 |
| | 44,000 | 20 | 27,000 | 38 |
| L(-) lactide/gamma-butyrolactone (95/5) copolymer | 59,000 | 12 | 42,000 | 29 |

¹ Inherent viscosity = 2.5, 10X draw, 0.008 inch diameter.

² Inherent viscosity = 2.5, 10X draw, 0.008 inch diameter.

³ Chromic gut (0.009-0.010 inch diameter).

⁴ Chromic gut (0.010-0.012 inch diameter).

⁵ After U.S. Pharmacopoeia

⁶ Inherent viscosity (bulk polymer) = 3.0 (spun filament) = 1.6, 10X draw, 0.007 inch diameter.

As will be apparent from Table I, the inherent viscosity of the spun filament, i.e., the oriented filament, may be somewhat less than that of the bulk polymer or copolymer, for during the extrusion operation some degradation of the polymer may occur depending on the extrusion conditions employed. If the sutures are sterilized by high energy radiation, there may be a further lowering of the molecular weight of the polymer, and a resulting decrease in tensile strength. However, by starting with lactide polymers and copolymers having inherent viscosities of at least 1, the sutures prepared therefrom are entirely satisfactory if one minimizes degradation during sterilization, even though there may be some loss in inherent viscosity due to extrusion and orientation.

The filaments of this invention are further characterized by their hydrolysis behavior and absorbability. On treatment with boiling water for 100 hours, they lose at least 20, and preferably at least about 50 percent, of their weight. On treatment with boiling water for a period of 50 hours, the copolymers lose at least about 8 percent of their weight, and preferably they lose at least about 35 percent of their weight.

By varying the type and amount of comonomer employed, the rate of hydrolysis (absorption) of the suture can be controlled. In contrast to the highly variable absorption rates of catgut, the absorption of polylactide polymers is relatively more independent of the place in the body where used and of the condition of the patient. Since the hydrolysis rate of a particular lactic acid polymer is constant at a fixed temperature, say, at 37° C., absorption can be speeded up, for instance, by using different copolymers. For example, poly-L-lactide was 15.3 percent absorbed in the back muscle of a rat after 270 days. Under comparable conditions, L(-)-lactide/DL-lactide (97/3) copolymer was 18.5 percent absorbed, L(-)-lactide/DL-lactide (95/5) copolymer was 29.0 percent absorbed, L(-)-lactide/glycolic (95/5) copolymer was 27.3 percent absorbed, and chromed catgut was 67 percent absorbed. The rate of absorption of a copolymer of L(-)-lactide and glycolide increase with increasing amounts of glycolide in the polymer chain.

As already indicated, high tensile strength is an exceedingly desirable characteristic for suture materials. The filaments of the present invention are characterized by having a tensile strength of at least 25,000 p.s.i., preferably above 40,000 p.s.i. Some have tensile strengths ranging up to 100,000 p.s.i. and higher. Their knot strengths, expressed in lbs. of pull, exceed the minimum limits set for absorbable sutures by the U.S. Pharmacopoeia, i.e., from 0.125 lb. for a 0.001-0.002 inch filament to 25 lbs. for a 0.036-0.040 inch filament.

In preparing the polymers and copolymers from which the filaments of this invention are made, the appropriate intermolecular cyclic ester or intramolecular cyclic ester (lactone) of the hydroxy acid is employed. These can be derived from pure D(-) or L(-) lactic acids, the optically inactive DL-lactic acid mixture, any desired mixtures of pure D(-)-lactic and

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L(+)-lactic acids, and other alpha, beta, or gamma-hydroxy acids, about which more will be said later. In general, it is preferred, for the preparation of lactic acid homopolymers and for the introduction of lactide repeating units into copolymers to use as a starting material a lactide derived from either the pure L(+)-acid or pure D(-)-acid because the polymers obtained therefrom have a higher melting point than those derived from the DL-lactic acid mixtures, are much less water sensitive, are stronger, and have a greater degree of crystallinity. For example, the polylactides from the DL-acid melt at 130° to 140° C., whereas those from the L(+)-acid melt at 145° to 175° C. The polylactides from the L(+)-acid or D(-)-acid are less sensitive to alcohol, a commonly used disinfecting medium in surgery, than those from the DL-acid. The L(+)-form is more readily available than the D(-)-acid and hence is particularly preferred. It is to be understood that the various lactides can be made from the corresponding lactic acids by a variety of published methods including that described in Schneider U.S. Pat. No. 2,703,316.

Table II, below, summarizes data comparing the properties of polymers prepared from L(-) lactide with those prepared from DL-lactide.

TABLE II

| | DL-lactide | Polymer from L(-) lactide |
|--|--------------------------------------|--------------------------------------|
| inherent viscosity | 0.7-2.0 | 0.7-3.5 |
| melting point | 130°-140° C. | 145°-175° C. |
| optical activity | no | yes (-184°) |
| solubility | CHCl ₃ , benzene, acetone | CHCl ₃ , benzene, acetone |
| density | 1.26 | 1.26 |
| tensile strength at break (monofilament) | 20,000 | 70,000 |
| elongation at break (monofilament) | 40,000 p.s.i. | 100,000 p.s.i. |
| tensile strength at break (dry film) | 15-30 percent | 15-30 percent |
| inherent viscosity (film) | 26,000 p.s.i.* | 29,000 p.s.i.* |
| elongation at break (film) | 1.20* | 1.23* |
| | 48 percent* | 23 percent* |

In general, the tensile modulus, melting point, and specific rotation of a lactic acid polymer is maximum for the homopolymer of a single-antipodal species and decreases with increasing amounts of the other antipodal species in the polymer chain. This characteristic of lactic acid copolymers is an advantage since it permits one to choose a copolymer composition that can be extruded to form filaments which have improved flexibility, without appreciable sacrifice in strength.

* Taken from U.S. Pat. No. 2,758,987.

In preparing copolymers, the repeating units derived from comonomers discussed above are introduced by use of the appropriate cyclic esters. For repeating units derived from alpha-hydroxy acids, these are usually the intermolecular cyclic esters containing six-membered rings, e.g., glycolide. For repeating units derived from beta- or gamma-hydroxy acids, the monomeric lactones, e.g., beta-propiolactone and gamma-butyrolactone, are usually used.

The polymer filaments of the present invention may be woven, braided, or knitted either alone or in combination with nonabsorbable fibers such as nylon, polypropylene, ORLON, DACRON, or TEFLON to form tubular structures having use in the surgical repair of arteries, veins, ducts, esophagi and the like. The manufacture of such tubular structures wherein the wall of the tube is fabricated of absorbable and nonabsorbable threads is described in U.S. Pat. Nos. 3,304,557; 3,108,357, and 3,463,158, the teachings of which are incorporated herein by reference. Inasmuch as the polylactide filaments are thermoplastic such tubular grafts may be crimped on a mandrel at elevated temperature and upon cooling to room temperature, will retain the crimp.

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Tubular structures of polylactide filaments may be prepared that are resistant to radial compression and expansion by applying a helical wrapping of polypropylene monofilament around the external surface of the tube and fusing the polypropylene to unite the helical wrapping with the polylactide filaments in the external surface of the tube as illustrated in U.S. Pat. No. 3,479,670.

The polymers of the present invention are also useful in the manufacture of cast films and other solid surgical aids such as scleral buckling prostheses. Thus, cylindrical pins, screws, reinforcing plates, etc., may be machined from the cast polymer having in vivo absorption characteristics depending upon the polymer composition and molecular weight.

The invention will appear more clearly from the following detailed description when taken in connection with the accompanying drawings which show by way of example preferred embodiments of the inventive idea. Referring now to the drawings:

FIG. 1 is a perspective view of a needle-suture combination.

FIG. 2 is a perspective view of a suture-needle combination within a hermetically sealed container;

FIG. 3 illustrates a screw machined from the polymer of the present invention;

FIG. 4 is a cross-sectional view of a composite yarn containing filaments of different composition and;

FIG. 5 is a plan view of a knitted fabric.

In preparing the filaments of this invention, it is essential to use polymers made from highly-purified lactides. For example, for excellent results L(-) lactide should have a melting point of at least 96° C. and a specific rotation greater than -295°. The polymerization is effected by heating the lactide above its melting point, but below about 215° C. in the presence of a polyvalent metal oxide or compound thereof, under anhydrous conditions in an inert atmosphere.

Specially useful catalysts are zinc oxide, zinc carbonate, basic zinc carbonate, diethylzinc, titanium, magnesium or barium compounds, litharge, stannous octoate and the like.

The amount and type of catalyst used determine the particular temperature and time required to produce polymer useful for conversion to the filaments of this invention. Thus, the amount can be as low as 0.001 weight percent or as high as 2 weight percent. As a rule, the lower the amount of catalyst, the longer the time required to produce polymer of a given inherent viscosity and, conversely, the higher the catalyst concentration, the shorter the time. The best balance is usually obtained employing from 0.02 weight percent to 1 weight percent of catalyst.

In general, it is desirable to agitate the reaction mixture continuously during the polymerization in order to produce a homogeneous polymer at good conversions and to conduct the reaction in two steps, the first being carried out at a lower temperature than the second, or finishing step. Other methods, such as those disclosed in U.S. Pat. Nos. 2,703,316 and 2,758,987 can be used in making the polymers.

The following is a brief description of a method for preparing the polymer useful for conversion to the filaments of this invention. Lactide, purified by several crystallizations from carbon tetrachloride, is placed with one or more solid comonomers in a thoroughly dried reactor equipped with a stirring bar, nitrogen inlet tube, and a drying tube filled conveniently with anhydrous magnesium sulfate or calcium chloride. Nitrogen, which has been dried by passage through anhydrous magnesium sulfate or calcium chloride, is introduced immediately above the reaction mixture and heating and stirring are started. When the temperature of the reaction mixture has reached about 100° C., the nitrogen inlet is replaced by a thermometer, and from about 0.001 to 2 weight percent of an oxide or salt of group II metal of atomic number 12 through 56, or litharge is added. In the case of copolymerization with a liquid comonomer the liquid comonomer is preferably added after the lactide has melted. Heating is continued until polymer having an inherent viscosity of at least 1 at 0.1 percent concentration in benzene at 25°

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C is obtained. This may require from a few minutes up to 25 or more hours, depending upon the catalyst used.

Polymer, produced as above, may be suitably further treated by cutting it into small pieces, dissolving in a suitable solvent, for example, benzene, toluene, or xylene, and the polymer precipitated by pouring the solution into a large volume of a nonsolvent for the polymer, desirably hexane. The precipitated polymer is removed by filtration, transferred to a blender and a nonsolvent for the polymer is added. The blender is started and after a homogeneous mixture has been obtained, the mixture is filtered. The polymer is allowed to dry on the filter and is then transferred to a vacuum oven. After drying overnight at 100° C., the polymer is removed from the oven and allowed to cool to ambient temperature.

As already indicated, the polymer material can be converted to filaments by melt-extrusion and also by spinning from solution. The diameter of the resulting filaments may be as small as 0.001 inch or less for the individual strands making up the multifilament structures and as large as 0.045 inch for very heavy monofilament sutures. Generally, however, the filaments of this invention will not have a diameter greater than 0.020-0.025 inch. Preferred are monofilaments having diameters of about 0.001-0.020 inch and multifilament structures having individual filaments of from less than 0.00025 to 0.003 inch diameter.

It will be understood that spinning and drawing may be done singly or in multiples. To prepare multifilament braided sutures, one may take either monofilaments or groups of filaments to braid.

Spinnerets having orifice sizes of 0.005 inch or larger, say, up to 0.150 inch, are suitable for spinning monofils. In spinning from solution, the solution may be extruded either into an atmosphere heated up to or above the boiling point of the solvent or into a nonsolvent for the polymer, e.g., hexane.

After spinning, the polylactide polymer and copolymer filaments are drawn to effect orientation and to improve tensile strength. This is accomplished by drawing (permanently elongating) the filaments at a temperature between 50° C. and 140° C., preferably between 90° C. and 135° C. the preferred draw ratio being from 3:1 to 11:1. The drawing step may be conducted in one or more steps, in air or in a bath containing a liquid nonsolvent for the polymer, e.g., glycerol or water. This drawing brings about a marked increase in tensile strength and molecular orientation, as measured by the X-ray orientation angle.

Following the drawing, the filaments may be subjected to annealing. This may be carried out by running the oriented filaments from a feed roll to a takeup roll and heating the filaments between the rolls, with the takeup roll rotating at a speed ranging from the same speed of the feed roll to a speed 4 percent slower than that of the feed roll. At the first-mentioned speed ratio, essentially no shrinkage will take place, and at the second-mentioned speed ratio shrinkage will take place up to 4 percent of its length. As a consequence of this annealing, the filaments undergo essentially no shrinkage under the action of body fluids, when used as sutures.

Instead of spinning the polylactide polymers into filaments, it is possible to extrude or cast it into films, which are then drawn and annealed. The films thus treated can be cut into narrow strips for use as sutures. In the preferred embodiment the sutures are made from filaments.

As best illustrated in FIG. 1, if the polylactide filaments 12 are to be used for suturing, one end thereof may be inserted in a drilled needle 13 and securely fastened in place by swaging to form a needle and suture combination.

Polylactide filaments, unlike catgut, are adversely affected by moisture and tubing fluid. For this reason, polylactide prostheses are packaged dry in a hermetically sealed package a preferred form of which is shown in FIG. 2. Referring now to FIG. 2, there is shown a surgical package indicated generally as 14 having disposed therein a coil of polylactide suture 12 one end of which is attached to a needle 13. The needle and suture are positioned within a cavity 16 that is evacuated or

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filled with a dry atmosphere such as nitrogen. The package is fabricated of two sheets of aluminum foil or aluminum foil plastic laminate material and heat sealed or bonded with adhesive at the skirt 18 to hermetically seal the cavity and isolate the contents of the package from the external atmosphere.

It is to be understood that minor amounts of inert additives such as coloring materials and plasticizers can be incorporated in the sutures by being mixed with the copolymers by known techniques. Any of a variety of plasticizers such as, for instance, glyceryl triacetate, ethyl benzoate, and diethyl phthalate can be used to advantage, especially with poly-L lactide. Preferred plasticizers for the glycolide copolymers are dibutyl phthalate and bis 2-methoxyethyl phthalate. The amount of plasticizer may vary from 1-40 percent based on the weight of the polymer. Not only does the plasticizer render the filaments more pliable and more easy to handle, but it also helps in spinning. By the term "inert" is meant materials that are inert chemically to the polymer, and are inert to living tissue, i.e., do not cause any of the adverse effects discussed on page 2 of this specification.

The present invention may be further illustrated by the following examples:

EXAMPLE I

Filaments having a diameter of 11.5 to 12.5 mils, a modulus of 1.04×10^8 , tensile strength of 47,000 lb./sq. in., a knot strength of 37,000 lb./sq. in., and an elongation at break of 21 percent, were prepared by spinning polymer from L(-) lactide, said polymer having an inherent viscosity of 2.44 (measured at 0.1 percent concentration in benzene at 25°C.), from melt at 190°C., and drawing to 6:1 ratio in glycerol at 95°C. Some of the filaments were annealed taut at 126°C. and others at 100°C. as shown in more detail in table III which follows:

TABLE III

| Annealed Taut at 126°C. for 5 Min | Shrinkage |
|---|--------------|
| Placed relaxed in oven at 126°C. for 5 minutes | 7.4 percent |
| Control (i.e., not annealed) | 28.2 percent |
| Placed relaxed in water at 100°C. for 5 minutes | 13.0 percent |
| Control | 28.2 percent |
| Placed relaxed in water at 77°C. for 5 minutes | 1.4 percent |
| Control | 18.0 percent |
| Annealed Taut at 100°C. for 5 Min | |
| Placed relaxed in oven at 100°C. for 5 minutes | 11.0 percent |
| Control | 21.4 percent |
| Placed relaxed in water at 77°C. for 5 minutes | 7.4 percent |
| Control | 18.0 percent |

Annealed filaments such as described above are particularly useful as sutures as evidenced from example II.

EXAMPLE II

A polymer of L(-) lactide, said polymer having an inherent viscosity of 1.4, was melt spun at 160° to 170°C. into a monofilament. The filament was then drawn to four times the undrawn length by passage over a metal plate heated to 90°C. The filament obtained measured 0.007 inch in diameter. To improve dimensional stability, the drawn monofilament was annealed for 3 minutes at 90°-95°C. while under tension. The drawn, annealed filament was cut to convenient length and sterilized by being placed in polyethylene bags, which were sealed and exposed to two passes under a Van de Graaff beam of 2 million electron volts (1 to 1.5 Mrads per pass). Some of the bags contained dry monofilament, some contained

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monofilament in water and some contained monofilaments in ethyl alcohol.

The effect of annealing can be seen by these observations. When the annealed monofilament was heated in a dry oven at 95°C. for 3 minutes in a relaxed state, it shrank less than 4 percent. By contrast, an identical monofilament that had not been annealed shrank 25 percent. The annealed monofilament at 77°C. in water for 5 minutes shrank 1.4 percent.

In another experiment, the annealed monofilament was implanted in the abdominal cavity of a young adult male rat. After 16 days the implantation was removed. It had undergone less than 2 percent shrinkage.

The monofilaments thus obtained were used to connect severed muscle tissue in rats and in dogs in accordance with the following procedure:

A midline incision was made in the rat's abdominal skin, the skin was peeled back, and two small slits were then made in the abdominal muscles, one on either side of the midline. Each rat was sutured with several loops of the sterilized monofilaments prepared as above in one incision. Each rat had, as a control, either plain or chromic catgut suture in the other incision (size 4-0, 0.006-0.008 inch diameter). The skin was then closed and clamped. The rats were observed at regular intervals.

The sterilized monofilaments were tested for suturing dogs as follows: a midline incision about 3 to 4 inches long was made in the skin over the abdomen of a 6-month old dog. The skin was separated from the abdominal musculature and retracted with conventional retractors. Three incisions about 1 inch long were made through the abdominal musculature. One incision was closed with polylactic acid suture material, the other incisions were sutured with commercial catgut sutures (U.S.P. type A plain, size 4-0, and type C medium chromic, size 4-0).

Rats were sacrificed at intervals of 2, 4, 7, 14, 28, 59, 91, and 140 days. Dogs were sacrificed at 14, 23, and 50 days. In these examinations it was observed that the polylactic acid monofilaments were more slowly absorbed than plain gut. Further, it was observed that there was less general tissue reaction with the polylactic acid, as shown by gross appearance and by examination of histological sections.

EXAMPLE III

Polymer from L(-) lactide having an inherent viscosity of 3.11 at 0.1 percent concentration in benzene at 25°C., prepared by previously described methods, was converted to sutures by melt spinning, drawing, and annealing as described in example I.

EXAMPLE IV

Monofilaments of poly-DL-lactic acid, having an inherent viscosity of 1.42 at 0.1 percent concentration in benzene at 25°C., were tested as sutures after having been sterilized by two passages under a 2 Mev. electron beam at 1 to 1.25 Mrads. per pass. The sterilized monofilaments (0.006-0.008 inch diameter) were tested in suturing rats as follows:

A midline incision was made in the rat's abdominal skin, the skin was peeled back, and two small slits were then made in the abdominal muscles, one on either side of the midlines. Each rat was sutured with several loops of the sterilized monofilament, prepared as above in one incision and with a catgut suture as control in the other incision (unchromed, size 4-0, 0.006-0.008 inch diameter). The skin was then closed and clamped. The rats were observed at regular intervals. After approximately one month, the poly-DL-lactic acid sutures were about 50 percent hydrolyzed; tissue reaction was minimal to absent with no evidence of granuloma formation and adhesions. In the rats sutured with catgut, the catgut absorbed to about 60 percent after about 1 month, but there was pronounced tissue reaction with evidence of adhesions and granulation.

After about 60 days, both the polylactic acid and catgut sutures were absorbed, but the rats sutured with the catgut showed more scar tissue than the rats sutured with the polylactic acid.

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200-78.5

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,636,956 Dated January 25, 1972

Inventor(s) Allan K. Schneider

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Col. 11, Table VI, under "Mole %", second occurrence,
line 2 : -75- has been omitted.

Col. 11, Table VI, under "Grams", second occurrence,
line 2 : should read -71.4-.

Col. 12, line 8 : the degree sign should appear after "85".

Col. 12, line 59 : "Example 59" should read -Example XVIII-.

Col. 13, Table IX : the last number in the first line
"Days post Implantation" should read -15-; the last
number in second line should read -0.4-; the last number
in last line should read -2.4-.

Col. 15, Claim 7 : "107" should read -1-.

Col. 15, Claim 15 : "114" should read -8-.

Signed and sealed this 28th day of November 1972.

(SEAL)
Attest:

EDWARD M. FLETCHER, JR.
Attesting Officer

ROBERT GOTTSCHALK
Commissioner of Patents

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With rabbits, the suture material was found to be completely unabsorbed before about 38 days, irrespective of whether it was plain catgut or polylactic acid. However, the rabbits which were stitched with the polylactic acid sutures showed no adverse tissue reactions, with no tissue walling off or covering over of the suture material, in contrast to the behavior of catgut.

A midline incision of about 3 to 4 inches long was made in the skin over the abdomen of a 6-month old dog. The skin was separated from the abdominal musculature and retracted with conventional retractors. Two incisions about 1 inch long were made through the abdominal musculature. The right side incision was closed with polylactic acid suture material (size 4-0). The left incision was sutured with catgut (U.S.P. type A plain, size 4-0). After 4 days the polylactic acid was intact with no evidence of granulation or adhesion. At the end of 14 days,

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After 90 Days in Distilled Water at
37° C.

Inherent Viscosity
Tensile strength
Weight loss

0.38
19,000 p.s.i.
2.6 percent

EXAMPLES VI-XIII

A number of other L(-) lactide copolymers were prepared and spun into filaments by the method of example V. When the comonomer was a liquid at ordinary temperature (beta-propiolactone, gamma-butyrolactone, or pivalolactone), it was added to the lactide only after the lactide had been fused. The bulk polymer properties, spinning conditions, and filament properties of these copolymers are summarized in the following table.

TABLE IV

| | Examples | | | | | | | |
|---|---------------------|---------------------|---------------------|---------------------|----------------------|--------------------------|---------------------------|---------------------|
| | VI | VII | VIII | IX | X | XI | XII | XIII |
| Weight percent comonomer | 7.3%
DL-lactide | 10%
DL-lactide | 15%
DL-lactide | 3%
glycolide | 10%
glycolide | 5%
beta-propiolactone | 5%
gamma-butyrolactone | 5%
pivalolactone |
| Inh. visc. (bulk) | 2.67 | 2.50 | 2.30 | 2.53 | 2.32 | 1.31 | 2.29 | 2.66 |
| Spinning temp., ° C. | 190 | 205 | 200 | 210 | 195 | 170 | 170 | 170 |
| Draw ratio | 8.8 | 8.1 | 7.5 | 8.6 | 8.0 | 115 | 115 | 100 |
| Drawing temp., ° C. | 128 | 125 | 100 | 105 | 100 | 115 | 115 | 100 |
| Inh. visc. (drawn fil.) | 1.75 | 1.75 | 1.47 | 1.84 | 1.70 | 1.73 | 1.41 | 1.41 |
| Diameter (mil.) | 11.5 | 11.0 | 12.5 | 10.5 | 9.5 | 9.4 | 9.4 | 9.4 |
| Ten. strength (p.s.i.) | 53,300 | 61,000 | 53,000 | 77,000 | 47,800 | 59,000 | 78,000 | 78,000 |
| Elong. at break, percent | 20 | 20.7 | 18.5 | 11 | 32 | 17 | 22 | 22 |
| Modulus (p.s.i.) | 1.4x10 ⁸ | 1.1x10 ⁸ | 1.1x10 ⁸ | 1.1x10 ⁸ | 0.48x10 ⁸ | 1.2x10 ⁸ | 1.2x10 ⁸ | 1.2x10 ⁸ |
| Knot strength (p.s.i.) | 37,500 | 37,100 | 30,000 | 43,000 | 27,000 | 42,000 | 48,000 | 48,000 |
| Shrinkage (H ₂ O/100° C./30 min.), percent | 13 | 27.8-44 | 7.2 | 12 | 73 | 115 | 115 | 115 |
| Wt. loss (H ₂ O/100° C./30 hrs.), percent | 44 | 48 | 65 | 45 | | | | |
| After 30 days in water at 37° C. | | | | | | | | |
| Inh. visc. (drawn fil.) | | 0.54 | | 0.56 | | | 0.81 | 0.72 |
| Ten. strength (p.s.i.) | | 23,800 | | 20,000 | | | 5.6 | 9.3 |
| Wt. loss, percent | | 2.3 | | 7.4 | | | | |
| After 90 days in water at 37° C. | | | | | | | | |
| Inh. visc. (drawn fil.) | | | | 0.34 | | | 0.54 | 0.35 |
| Ten. strength (p.s.i.) | | | | 12,000 | | | 7.1 | 3.5 |
| Wt. loss, percent | | | | 12.1 | | | | |

^a About.

the dog was again examined and at the time the incision closed with the catgut showed intense inflammatory reaction. In contrast, the incision closed with the polylactic acid suture was free of granuloma formation, and the scar was clearly visible, i.e., no inflammation was evident. In both cases, however, the suture material had been absorbed by the tissue.

EXAMPLE V

A mixture of 95 parts by weight of L(-) lactide and 5 parts by weight of DL-lactide was fused under nitrogen, and there was added 0.125 part by weight of diethylzinc as a 25 percent solution in heptane. The mixture was heated at 105° C. for 1 hour at atmospheric pressure in an atmosphere of nitrogen. The solid L(-) lactide/DL-lactide (95/5) copolymer thus obtained had an inherent viscosity of 2.63 (0.1 percent solution in benzene at 34.5° C.). The copolymer was ground to a fine powder, which was in turn pressed to a plug suitable for use in an extrusion-spinning apparatus. Filaments of the copolymer were spun at about 200° C. through a 35 mil spinneret and were drawn to 6.4 times their original length in glycerol at about 120° C. The drawn filaments had the following properties:

| | |
|--|-----------------------------|
| Inherent Viscosity | 1.7 |
| Diameter | 12.5 mils |
| Tensile Strength | 58,500 p.s.i. |
| Elongation at break | 20 percent |
| Modulus | 1.08x10 ⁸ p.s.i. |
| Knot strength | 37,000 p.s.i. |
| Shrinkage after 5 minutes in water at 77° C. | 23 percent |
| Weight loss after 50 hours in boiling water | 39 percent |
| After 90 Days in Distilled Water at 37° C. | |
| Inherent Viscosity | 0.53 |
| Tensile strength | 19,000 p.s.i. |
| Weight loss | 2.6 percent |

EXAMPLES XIV-XV

Copolymers of L-lactide with the intermolecular cyclic esters of alpha-hydroxybutyric acid and alpha-hydroxyheptanoic acid were made by essentially the method of example V.

A mixture of 44.2 parts of L-lactide and 5.8 parts of the cyclic ester of alpha-hydroxybutyric acid was fused under nitrogen, and there was added 0.08 part of 25 percent solution of diethylzinc in heptane. The mixture was heated at 105°-108° C. for 3 hours at atmospheric pressure in an atmosphere of nitrogen. The resulting copolymer of L-lactide and the intermolecular cyclic ester of alpha-hydroxybutyric acid (88.4/11.6) had an inherent viscosity of 2.15 (0.1 percent solution in benzene).

The copolymer of L-lactide and the intermolecular cyclic ester of alpha-hydroxyheptanoic acid (90/10) was prepared similarly from 45 parts of L-lactide, 5 parts of cyclic ester, and 0.08 part of 25 percent solution of diethylzinc in heptane. After the mixture was heated for 3 hours, the resulting polymer had an inherent viscosity of 2.28.

The spinning conditions and filament properties of these copolymers are summarized in table V.

The intermolecular cyclic esters of alpha-hydroxybutyric acid and alpha-hydroxyheptanoic acid were prepared essentially by the method of Bischoff and Walden, Ann. 279, 100 (1895). The sodium salts of the corresponding alpha-bromo acids were made from the acids and sodium methoxide in an ethyl ether/ethyl alcohol mixture. The cyclic esters were made by heating the sodium salts to 300°-315° C. under reduced pressure. The butyric acid derivative was purified by distillation at 78°-85° C./0.07 mm. and by crystallization from ethyl alcohol/petroleum ether, with cooling in solid carbon dioxide. The heptanoic acid derivative was purified by crystallization from pentane, with cooling in solid carbon dioxide, and from

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ethyl alcohol. Both cyclic esters were characterized by elemental analyses and infrared absorption spectra

TABLE V

| Example | XIV | XV |
|---|--|---|
| 9 Comonomer (by weight) | 11.6% isomolar ester cyclic ester of alpha-hydroxybutyric acid | 10% isomolar ester cyclic ester of alpha-hydroxyphenylacetic acid |
| Inh. viscosity (bulk) | 2.15 | 2.38 |
| Spinning temperature | 185° C | 100° C |
| Draw ratio | 10* | 98* |
| Draw temperature | 94° C, 122° C** | 143** |
| Inherent viscosity | 1.42** | 1.63** |
| Tensile strength | 66,300 | 59,100 |
| Elongation at break (p.s.i.) | 22.3% | 18.3% |
| Modulus (p.s.i.) | 1.04x10 ⁹ | 0.95x10 ⁹ |
| Shrinkage (H ₂ O/77° C/5 mm) | 20.6% | 55.0% |
| Weight loss (H ₂ O/100° C/48 hrs.) | 60.5% | 63.6% |

* This filament was drawn in two stages. In the first stage, it was drawn 7X (draw ratio = 7) at 94° C. in the second, it was drawn at 122° C. to an extent sufficient to give an overall draw ratio of 10.

** Measured on undrawn filament. The inherent viscosities of the filaments of examples V, XIII were measured on drawn filaments.

EXAMPLE XVI

A mixture of 206 g. of powdered L-lactide/DL-lactide (90/10) copolymer and 0.6182 g. of the monosodium salt of 4-[4-(N-ethyl-p-sulfobenzylamino)diphenylmethylene]-1-(N-ethyl-N-p-sulfoniumbenzyl)-Δ^{1,2}-cyclohexadienimine][F D & C (Food, Drug, and Cosmetic) Green No. 1] was rotated in a Fisher-Kendall mixer for 48 hours at room temperature. The resulting homogeneous mixture was pressed to a plug and spun into green monofilaments by essentially the method of example V.

EXAMPLE XVII

The weighed amounts of L(-) lactide melting at 98°-99° C. and having a specific rotation (sodium D-line, 25° C.) of -295 to -300, and glycolide (m.p. 82.8-84.5° C.) are mixed in the quantities indicated below and added to a cylindrical tube containing stannous octoate catalyst and a magnetic stir bar. After sealing under 110 mm. of mercury pressure, the vessel is heated at 105° C. for 96 hours with magnetic stirring to yield a cylinder of solid copolymer. In each case, 0.0039 mol (0.1580 g.) of stannous octoate is used as the catalyst. The monomer/initiator ratio (A/I) is 1,500.

The reacting quantities and mol percent of the comonomers investigated in this example are summarized in the following table:

TABLE VI

| Mole % | GLYCOLIDE | | Moles | LACTIDE | | Moles |
|--------|-----------|-------|-------|---------|------|-------|
| | Grams | | Grams | Grams | | |
| 20 | 15.3 | 0.116 | 80 | 66.6 | 0.66 | |
| 24 | 19.1 | 0.163 | 76 | 71.9 | 0.69 | |
| 30 | 26.2 | 0.17 | 70 | 58.4 | 0.61 | |
| 35 | 33.6 | 0.28 | 65 | 54.7 | 0.38 | |
| 40 | 36.7 | 0.33 | 60 | 50.4 | 0.35 | |
| 45 | 36.2 | 0.36 | 55 | 46.1 | 0.32 | |
| 50 | 33.6 | 0.39 | 50 | 41.8 | 0.29 | |
| 54 | 39.2 | 0.34 | 46 | 40.1 | 0.28 | |
| 56 | 47.1 | 0.41 | 30 | 25.1 | 0.17 | |

A similar series is run using tetraphenyl tin as a catalyst at an A/I of 2,000 with similar results.

Each copolymer (from 20 mole percent glycolide to 70 mole percent glycolide) is extruded under pressure at a temperature of 10°-220° C. through a 35-mil orifice. The extruded fiber has a diameter of 33-36 mils and is drawn to five times its original length. The extruded fibers are heated to 70°-85° C. during this drawing step.

Strong resilient fibers having excellent tensile and dry knot strength are thus obtained, the physical characteristics of these fibers being summarized in the following table:

* Used 0.1780 g. of catalyst

TABLE VII

| Glycolide, mole percent | Diameter, mils | straight, lbs. | Diameter, mils | Dry knot, lbs. | Initial, lbs. | K/S |
|-------------------------|----------------|----------------|----------------|----------------|---------------|------|
| 20 | 18.9 | 8.87 | 18.4 | 6.96 | Ph | 0.82 |
| 20 | 12.4 | 6.96 | 12.1 | 4.42 | O | 0.66 |
| 25 | 14.7 | 9.14 | 14.2 | 6.61 | O | 0.73 |
| 25 | 14.5 | 8.66 | 14.2 | 4.17 | Ph | 0.66 |
| 30 | 13.1 | 8.28 | 13.1 | 4.80 | O | 0.69 |
| 30 | 14.1 | 10.2 | 14.2 | 6.34 | Ph | 0.78 |
| 35 | 14.2 | 8.38 | 14.2 | 4.53 | O | 0.64 |
| 40 | 14.2 | 10.2 | 14.2 | 4.7 | O | 0.80 |
| 45 | 14.1 | 11.4 | 14.1 | 7.17 | Ph | 0.73 |
| 50 | 14.1 | 10.0 | 13.4 | 4.76 | O | 0.64 |
| 50 | 14.1 | 11.2 | 14.0 | 4.59 | Ph | 0.76 |

NOTE: Ph=tetraphenyl tin, monomer/initiator ratio=1,000; O=stannous octoate, monomer/initiator ratio=1,500; K/S=dry knot straight pull ratio.

The biological behavior of the L(-) lactide glycolide copolymers prepared in accordance with the present example is summarized in table VIII. Sections of suture material are implanted subcutaneously in rats and removed at various intervals to determine changes in tensile strength and diameter. A large increase in the diameter of a suture following implantation is an indication of shrinkage (dimensional instability).

TABLE VIII

| Glycolide, mole percent | | Days post implantation | | | | |
|-------------------------|-------------------------|------------------------|------|------|------|------|
| | | 0 | 1 | 8 | 10 | 15 |
| 20 | Tensile strength (lbs.) | 10.1 | 8.8 | 6.7 | 4.2 | 4.0 |
| 20 | Diameter (mils) | 14.8 | 14.4 | 14.6 | 14.4 | 14.4 |
| 25 | Tensile strength (lbs.) | 10.1 | 8.8 | 4.0 | 3.3 | 3.0 |
| 25 | Diameter (mils) | 14.0 | 14.7 | 14.4 | 14.8 | 14.9 |
| 30 | Tensile strength (lbs.) | 10.3 | 9.3 | 4.4 | 3.0 | 1.4 |
| 30 | Diameter (mils) | 14.1 | 14.4 | 22.7 | 23.8 | 24.2 |
| 35 | Tensile strength (lbs.) | 10.1 | 8.8 | 1.5 | | |
| 35 | Diameter (mils) | 12.4 | 20.9 | 24.9 | | |
| 40 | Tensile strength (lbs.) | 9.9 | 8.4 | 3.7 | 0.0 | |
| 40 | Diameter (mils) | 14.0 | 23.8 | 27.4 | 28.1 | |
| 50 | Tensile strength (lbs.) | 9.9 | 8.2 | 1.4 | 0.0 | |
| 50 | Diameter (mils) | 14.0 | 24.0 | 24.4 | 41.0 | |
| 50 | Tensile strength (lbs.) | 8.8 | 7.9 | 0.2 | | |
| 50 | Diameter (mils) | 14.1 | 20.2 | 26.4 | | |

EXAMPLE VIII

Fifty-four and seven-tenths parts by weight of L(-) lactide (0.38 mols) melting at 98°-99° C. and having a specific rotation (sodium D-line, 25° C.) of -295 to -300 is mixed with 23.6 parts by weight (0.20 mols) of glycolide (m.p. 82.8°-84.5° C.) and 0.0039 mol (0.158 parts by weight) of stannous octoate in a dry PYREX glass flask containing a stir bar under dry nitrogen. The monomer/initiator ratio (A/I) is 1,500. The glass flask is sealed under 110 mm. of mercury pressure and the vessel is heated at 105° C. for 96 hours with magnetic stirring to yield a solid copolymer.

The 35 mole percent glycolide-lactide copolymer so obtained is extruded under pressure at an elevated temperature through a 35 mil orifice and drawn to five times the original length. The extruded fiber is heated to 70°-85° C. during this drawing step. The biological behavior of this 35 mole percent copolymer in rats is summarized in table IX.

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TABLE IX

| Days post implantation | 0 | 1 | 6 | 10 | 1 |
|--|------|------|------|------|---|
| Tensile strength, lbs. | 10.0 | 8.9 | 4.2 | 2.1 | 0 |
| Tensile strength, p.s.i. (X10 ³) | 60.0 | 52.3 | 25.2 | 13.6 | 2 |

A 35 mole percent copolymer, prepared as described above may be extruded to form a rod that can be oriented by drawing 3x at an elevated temperature. The rod so formed will have a tensile strength greater than 25,000 p.s.i.

Although this invention has been specifically illustrated with monofilaments, the products of the present invention may also be manufactured in the form of multifilaments, that may be braided to form sutures. Filaments suitable for braiding having a diameter in the range of 0.00025-0.003 inches may be conveniently obtained by dry spinning a L(-) lactide polymer dissolved in a suitable solvent. The manufacture of a braided size 2/0 suture from multifilament obtained by dry spinning a L(-) lactide copolymer is illustrated in the following example.

EXAMPLE XIX

A round-bottomed PYREX flask having a long neck is carefully cleaned, flame dried, evacuated and purged two times with dry nitrogen. To the flask is added under a dry nitrogen atmosphere:

251.42 parts glycolide (M.P. 82.8-84.3° C.) 30.19 wt. percent
533.52 parts L(-) lactide (M.P. 98°-99° C.) 69.61 wt. percent
1.558 parts stannous octoate, 0.20 wt. percent

The flask is evacuated to 125 mm. pressure and heated at 105° C. for 66 hours. The polymer so obtained (inherent viscosity in 0.1 percent chloroform solution = 3.2-3.4) is dissolved in dry 1,1,2-trichloroethane (distilled from phosphorous pentoxide) to give a clear 8 percent (W/W) solution (bulk viscosity 1,600 poise).

The spin dope (8 percent solution) is heated to 90° C. and extruded through a 10-hole 0.005 inch spinneret (capillary land/diameter = 2.4) at a rate of 3 milliliters per minute into a heated column 15 feet long and 6 inches in diameter. The temperature within the heated column varied from 128° C. at the bottom to 142° C. at the top and the column is swept with hot nitrogen (131-134° C.) at a rate of 5 cubic feet per minute. The extruded filaments are taken up on a reel at a linear speed of 150 feet per minute. The inherent viscosity of the filamentary material is 3.4 indicating no degradation during the spinning process. The copolymer filament is lustrous in appearance and has the following physical characteristics:

| | |
|------------------|------------------|
| Tensile Strength | 1.0 grams/denier |
| Elongation | 530 percent |
| Young's Modulus | 24 grams/denier |

The filament contains about 1.5 percent residual solvent.

The yarn from the takeup spool is 6-ply to 60 filaments and drawn 4.5 times at 75° C. and 25 feet per minute input speed through a tubular furnace swept with nitrogen. The drawn yarns prepared as described above have the following physical characteristics:

| | |
|------------------|----------------------|
| Tensile Strength | 2.8-3.3 grams/denier |
| Elongation | 26 percent |
| Young's Modulus | 30 grams/denier |

The individual filaments have a tensile strength of about 2.5-3.0 grams/denier; an elongation of about 38 percent and a Young's Modulus of about 45 grams per denier. The yarn is braided to form a size 2/0 braided suture, packaged in a dry atmosphere in a hermetically sealed container and sterilized by cobalt 60 gamma irradiation. The in vivo absorption characteristics of this braided suture material in rats are indicated in Table X.

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TABLE X

| | After days post implantation | | | | |
|--|------------------------------|----|----|----|----|
| | 0 | 1 | 6 | 10 | 15 |
| Tensile strength (X10 ³ p.s.i.) | 28 | 47 | 37 | 31 | 30 |

It will be noted from a comparison of table IX and table X that the braided structure obtained from yarn that has been dry spun from a suitable solvent (example XIX) retained in vivo tensile strength for a longer period of time than a melt extruded monofilament of similar composition (example XVIII). The improvement in in vivo tensile strength exhibited by the dry spun braided suture is such that the amount of glycolide in the lactide copolymer composition may be increased to 40 mole percent (34.8 weight percent glycolide, 65.2 weight percent L-lactide). A copolymer suture of this composition (40 mole percent glycolide 60 mole percent L-lactide) has tensile strength and absorption characteristics similar to catgut.

Multifilament yarns that contain polylactide filaments together with nonabsorbable filaments of DACRON, TEFLON, nylon, etc., are useful in the manufacture of vascular grafts. Such a multifilament yarn is illustrated in FIG. 4 wherein the nonabsorbable fiber is represented by the hatched fiber cross section 19. In FIG. 4, the fibers 20 are extruded from lactide polymer and copolymer compositions as described above. The relative proportions of absorbable filaments 20 and nonabsorbable filaments 19 may be varied to obtain the absorption characteristic desired in the woven fabric or tubular implants. Methods of weaving and crimping vascular prostheses are described in U.S. Pat. No. 3,096,560.

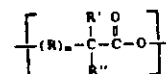
Composite fabrics of absorbable and nonabsorbable materials fashioned by textile processes including weaving, knitting, and fabricating by the nonwoven felting of fibers are described in U.S. Pat. No. 3,108,357 and U.S. Pat. No. 3,463,158. Similar techniques may be used in the manufacture of surgical aids wherein nonabsorbable fibers are combined with absorbable fibers composed of lactide polymers and copolymers. The surgical utility of "bicomponent filaments" containing absorbable and nonabsorbable components is described in U.S. Pat. No. 3,463,158, the teaching of which is incorporated herein by reference. Monofilaments of lactide polymers and copolymers may be woven or knitted to form an absorbable fabric having the structure illustrated in FIG. 5, useful surgically in hernia repair and in supporting damaged liver, kidney, and other internal organs.

The products of the invention are useful in surgical applications where an absorbable aid or support is required, for example, in the formation of surgical mesh, absorbable staple, artificial tendons, or cartilage material, and in other uses where a temporary aid during healing is needed. They may also be used to advantage in repairing hernias and in anchoring organs which have become loose.

As many apparently widely different embodiments of this invention may be made without departing from the spirit and scope thereof, it is to be understood that this invention is not limited to the specific embodiments thereof except as defined in the appended claims.

I claim:

1. A sterile surgical suture absorbable without causing unfavorable tissue reaction and essentially dimensionally stable within the body comprising an oriented synthetic polylactide polymer containing more than about 85 percent by weight of repeating units of one antipodal species of alpha-hydroxypropionic acid and no more than about 15 percent by weight of repeating units of the formula



where R is lower alkylene, m is an integer of 0 to 1, R' is selected from the class consisting of hydrogen and lower alkyl, and R'', which can be the same or different than R', is selected from the class consisting of hydrogen and alkyl of up to 22 carbons.

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bons when m is 0 and, when m is 1, R'' is selected from the class consisting of hydrogen and lower alkyl, said polylactide before being oriented being characterized by having an inherent viscosity of at least 1.2 at 0.1 percent concentration in benzene at 25°C and by losing at least about 20 percent of its weight on treatment with boiling water for a period of 100 hours, and being further characterized by exhibiting a tensile strength of from 40,000 to about 100,000 p.s.i. and by having a diameter of 0.0005–0.045 inches.

2. The suture of claim 1, packaged in a dry atmosphere within a hermetically sealed container.

3. The suture of claim 1, packaged within an evacuated hermetically sealed container.

4. The suture of claim 1, wherein the polylactide polymer is a poly-L(-) lactide containing up to 15 percent by weight of repeating units derived from DL-lactide.

5. The suture of claim 1, containing a minor amount of inert coloring agent and plasticizer.

6. The suture of claim 1, containing bis 2-methoxyethyl phthalate as a plasticizer.

7. A method of retaining living tissue in a desired location and relationship during a healing process which comprises:

sewing living tissue with the suture of claim 107, whereby said suture becomes imbedded in the tissue;

and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

8. The suture of claim 1, having a sterile needle attached to one end thereof.

9. The needle and suture combination of claim 8, packaged in a dry atmosphere within a hermetically sealed container.

10. The needle and suture combination of claim 8, packaged within an evacuated hermetically sealed container.

11. The needle and suture combination of claim 8, wherein said monofilament is a poly-L(-) lactide containing up to 15 percent by weight of repeating units derived from DL-lactide.

12. The needle and suture combination of claim 8, wherein said monofilament is a 95/5 weight percent copolymer of L(-) lactide and DL-lactide.

13. The needle and suture combination of claim 8, wherein said monofilament contains a minor amount of inert coloring agent and plasticizer.

14. The needle and suture combination of claim 8, wherein said monofilament contains bis 2-methoxyethyl phthalate as a plasticizer.

15. A method of retaining living tissue in a desired location and relationship during a healing process which comprises:

sewing living tissue with the suture of claim 114, whereby said suture becomes imbedded in the tissue; and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

16. A sterile surgical suture absorbable without causing unfavorable tissue reaction and essentially dimensionally stable within the body comprising a synthetic polylactide copolymer containing at least about 65 mole percent of repeating units derived from one antipodal species of alpha-hydroxypropionic acid and not more than about 35 mole percent of repeating units derived from alpha-hydroxyacetic acid, said polylactide being characterized by having an inherent viscosity of at least 1.2 at 0.1 percent concentration in a suitable solvent at 25°C, and by losing at least about 20 percent of its weight on treatment with boiling water for a period of 100 hours, and being further characterized by exhibiting a tensile strength of from 40,000 p.s.i. to about 100,000 p.s.i. and by having a diameter of 0.0005–0.045 inches.

17. The suture of claim 16, packaged in a dry atmosphere within a hermetically sealed container.

18. The suture of claim 16, packaged within an evacuated hermetically sealed container.

19. The suture of claim 16, wherein the polylactide copolymer contains about 35 mole percent of repeating units derived from alpha-hydroxyacetic acid.

20. The suture of claim 16, wherein the polylactide

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copolymer contains about 30 mole percent of repeating units derived from alpha-hydroxyacetic acid.

21. The suture of claim 16, wherein the polylactide copolymer contains about 25 mole percent of repeating units derived from alpha-hydroxyacetic acid.

22. The suture of claim 16, wherein the polylactide copolymer contains about 20 mole percent of repeating units derived from alpha-hydroxyacetic acid.

23. The suture of claim 16, wherein the polylactide copolymer contains about 15 weight percent of repeating units derived from alpha-hydroxyacetic acid.

24. The suture of claim 16, wherein the polylactide copolymer contains about 5 weight percent of repeating units derived from alpha-hydroxyacetic acid.

25. The suture of claim 16, containing a minor amount of inert coloring agent and plasticizer.

26. The suture of claim 16, containing bis 2-methoxyethyl phthalate as a plasticizer.

27. A method of retaining living tissue in a desired location and relationship during a healing process which comprises:

sewing living tissue with the suture of claim 16, whereby said suture becomes imbedded in the tissue;

and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

28. The suture of claim 16, having a sterile needle attached to one end thereof.

29. The needle and suture combination of claim 28, packaged in a dry atmosphere within a hermetically sealed container.

30. The needle and suture combination of claim 28, packaged within an evacuated hermetically sealed container.

31. The needle and suture combination of claim 28, wherein the polylactide polymer contains about 35 mole percent of repeating units derived from alpha-hydroxyacetic acid.

32. The needle and suture combination of claim 28, wherein the polylactide polymer contains about 30 mole percent of repeating units derived from alpha-hydroxyacetic acid.

33. The needle and suture combination of claim 28, wherein the polylactide polymer contains about 25 mole percent of repeating units derived from alpha-hydroxyacetic acid.

34. The needle and suture combination of claim 28, wherein the polylactide polymer contains about 20 mole percent of repeating units derived from alpha hydroxyacetic acid.

35. The needle and suture combination of claim 28, wherein the polylactide polymer contains about 15 weight percent of repeating units derived from alpha-hydroxyacetic acid.

36. The needle and suture combination of claim 28, wherein the polylactide polymer contains about 5 weight percent of repeating units derived from alpha-hydroxyacetic acid.

37. The needle and suture combination of claim 28, wherein said monofilament contains a minor amount of inert coloring agent and plasticizer.

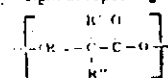
38. The needle and suture combination of claim 28, wherein said monofilament contains bis 2-methoxyethyl phthalate as a plasticizer.

39. A method of retaining living tissue in a desired location and relationship during a healing process which comprises:

sewing living tissue with the needle and suture combination of claim 28, whereby said suture becomes imbedded in the tissue;

and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

40. A sterile surgical suture absorbable without causing unfavorable tissue reaction and essentially dimensionally stable within the body in the form of a braided structure, comprising filaments of a synthetic polylactide polymer containing at least about 85 percent by weight of repeating units of one antipodal species of alpha-hydroxypropionic acid and no more than about 15 percent by weight of repeating units of the formula



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where R is lower alkylene, m is an integer of 0 to 3, R' is selected from the class consisting of hydrogen and lower alkyl, and R'' which can be the same or different from R', is selected from the class consisting of hydrogen and alkyl group of up to 22 carbons when m is 0 and, when m is 1, R'' is selected from the class consisting of hydrogen and lower alkyl, said polylactide being characterized by having an inherent viscosity of at least 1.2 at 0.1 percent concentration in benzene at 25° C. and by losing at least about 20 percent of its weight on treatment with boiling water for a period of 100 hours, at least 50 percent of the filaments making up the braided structure being oriented and the diameter of the filaments ranging from 0.00025 to 0.003 inches; and the braided structure itself being characterized by exhibiting a tensile strength of from 40,000 p.s.i. to about 100,000 p.s.i.

41. The suture of claim 40, packaged in a dry atmosphere within a hermetically sealed container.

42. The suture of claim 40, packaged within an evacuated hermetically sealed container.

43. The suture of claim 40, wherein the polylactide copolymer filaments that make up said braided structure contain up to 15 percent by weight of repeating units derived from DL-lactide.

44. The suture of claim 40, wherein the polylactide copolymer filaments that make up said braided structure are a 95/5 weight percent copolymer of L(-) lactide and DL-lactide.

45. The suture of claim 40, wherein the filaments that make up said braided structure contain a minor amount of inert coloring agent and plasticizer.

46. The suture of claim 40, wherein the filaments that make up said braided structure contain bis 2-methoxyethyl phthalate as a plasticizer.

47. A method of retaining living tissue in a desired location and relationship during a healing process which comprises: sewing living tissue with the suture of claim 40, whereby said suture becomes imbedded in the tissue; and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

48. The suture of claim 40, having a sterile needle attached to one end thereof.

49. The needle and suture combination of claim 48, packaged in a dry atmosphere within a hermetically sealed container.

50. The needle and suture combination of claim 48, packaged within an evacuated hermetically sealed container.

51. The needle and suture combination of claim 48, wherein the polylactide copolymer filaments that make up said braided structure contain up to 15 percent by weight of repeating units derived from DL-lactide.

52. The needle and suture combination of claim 48, wherein the polylactide copolymer filaments that make up said braided suture are a 95.5 weight percent copolymer of L(-) lactide and DL-lactide.

53. The needle and suture combination of claim 48, wherein the filaments that make up said braided suture contain a minor amount of inert coloring agent and plasticizer.

54. The needle and suture combination of claim 48, wherein the filaments that make up said braided suture contain bis 2-methoxyethyl phthalate as a plasticizer.

55. A method of retaining living tissue in a desired location and relationship during a healing process which comprises: sewing living tissue with the suture and needle combination of claim 47, whereby said suture becomes imbedded in the tissue; and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

56. A sterile surgical suture absorbable without causing unfavorable tissue reaction and essentially dimensionally stable within the body in the form of a braided structure comprising filaments of a synthetic polylactide copolymer containing at least 60 mole percent of repeating units derived from one an-

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tidal species of alpha-hydroxypropionic acid and no more than 40 mole percent of repeating units derived from alpha-hydroxyacetic acid, said polylactide being characterized by having an inherent viscosity of at least 1.2 at 0.1 percent concentration in a suitable solvent at 25° C. and by losing at least about 20 percent of its weight on treatment with boiling water for a period of 100 hours, at least 50 percent of the filaments making up the braided structure being oriented, and the braided structure itself being further characterized by exhibiting a tensile strength of at least 15,000 p.s.i. 10 days following implantation in an animal body.

57. The suture of claim 56, packaged in a dry atmosphere within a hermetically sealed container.

58. The suture of claim 56, packaged within an evacuated hermetically sealed container.

59. The suture of claim 56, wherein the polylactide copolymer contains about 35 mole percent of repeating units derived from alpha-hydroxyacetic acid.

60. The suture of claim 56, wherein the polylactide copolymer contains about 30 mole percent of repeating units derived from alpha-hydroxyacetic acid.

61. The suture of claim 56, wherein the polylactide copolymer contains about 25 mole percent of repeating units derived from alpha-hydroxyacetic acid.

62. The suture of claim 56, wherein the polylactide copolymer contains about 20 mole percent of repeating units derived from alpha-hydroxyacetic acid.

63. The suture of claim 56, wherein the polylactide copolymer contains about 15 weight percent of repeating units derived from alpha-hydroxyacetic acid.

64. The suture of claim 56, wherein the polylactide copolymer contains about 5 weight percent of repeating units derived from alpha-hydroxyacetic acid.

65. The suture of claim 56, wherein the filaments that make up said braided structure contain a minor amount of inert coloring agent and plasticizer.

66. The suture of claim 56, wherein the filaments that make up said braided structure contain bis 2-methoxyethyl phthalate as a plasticizer.

67. A method of retaining living tissue in a desired location and relationship during a healing process which comprises: sewing living tissue with the suture of claim 56, whereby said suture becomes imbedded in the tissue; and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

68. The suture of claim 56, having a sterile needle attached to one end thereof.

69. The needle and suture combination of claim 68, packaged in a dry atmosphere within a hermetically sealed container.

70. The needle and suture combination of claim 68, packaged within an evacuated hermetically sealed container.

71. The needle and suture combination of claim 68, wherein the polylactide copolymer filaments that make up said braided structure contain about 35 mole percent of repeating units derived from alpha-hydroxyacetic acid.

72. The needle and suture combination of claim 68, wherein the polylactide copolymer filaments that make up said braided structure contain about 30 mole percent of repeating units derived from alpha-hydroxyacetic acid.

73. The needle and suture combination of claim 68, wherein the polylactide copolymer filaments that make up said braided structure contain about 25 mole percent of repeating units derived from alpha-hydroxyacetic acid.

74. The suture of claim 68, wherein the polylactide copolymer filaments that make up said braided structure contain about 20 mole percent of repeating units derived from alpha-hydroxyacetic acid.

75. The needle and suture combination of claim 68, wherein the polylactide copolymer filaments that make up said braided structure contain about 15 weight percent of repeating units derived from alpha-hydroxyacetic acid.

76. The needle and suture combination of claim 68, wherein the polylactide copolymer filaments that make up said braided

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structure contain about 5 weight percent of repeating units derived from alpha-hydroxyacetic acid

77. The needle and suture combination of claim 68, wherein the filaments that make up said braided structure contain a minor amount of inert coloring agent and plasticizer

78. The needle and suture combination of claim 68, wherein the filaments that make up said braided structure contain bis 2-methoxyethyl phthalate as a plasticizer

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79. A method of retaining living tissue in a desired location and relationship during a healing process which comprises sewing living tissue with the needle and suture combination of claim 68, whereby said suture becomes imbedded in the tissue, and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process

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Feb. 27, 1979

by et al.

ISOMORPHIC COPOLYOXALATES AND
SUTURES THEREOFInventors: Shalaby W. Shalaby, Long Valley;
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3/1.5; 128/92 B; 128/92 C; 128/334 R;
128/335.5; 260/860; 528/307Field of Search 260/75 R, 860; 3/1,
3/1.4, 1.5; 128/92 B, 92 C, 334 R, 335.5

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Primary Examiner—Benjamin R. Padgett

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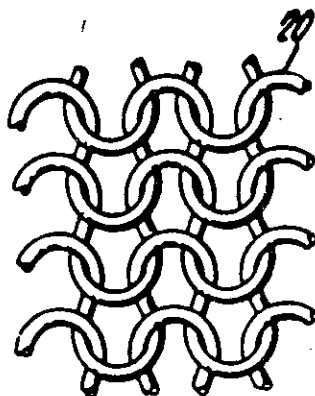
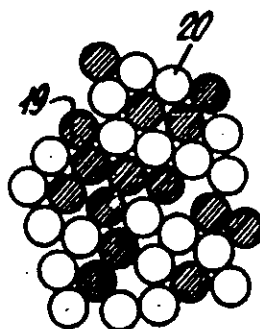
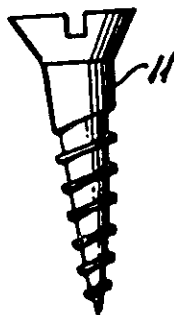
Attorney, Agent, or Firm—Wayne R. Eberhardt

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ABSTRACT

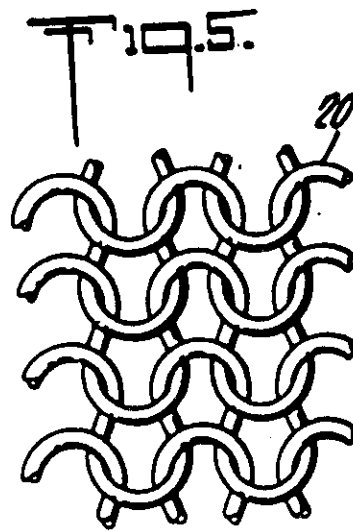
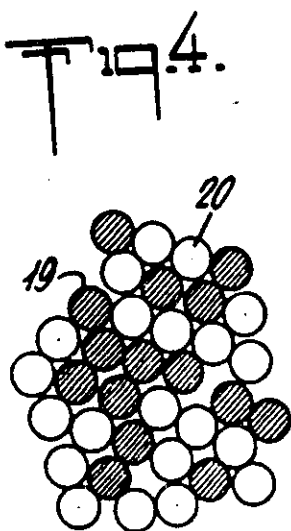
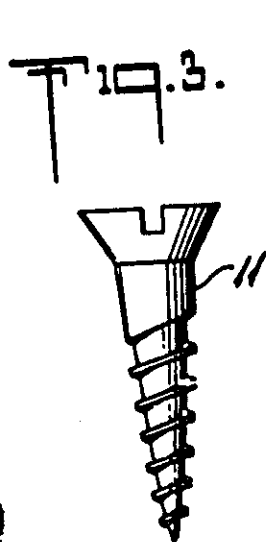
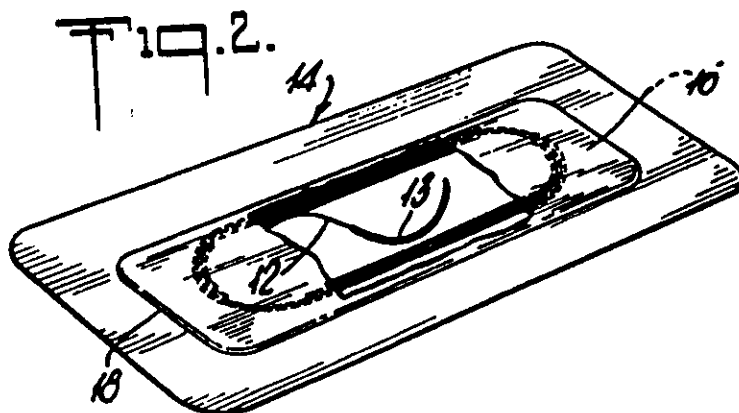
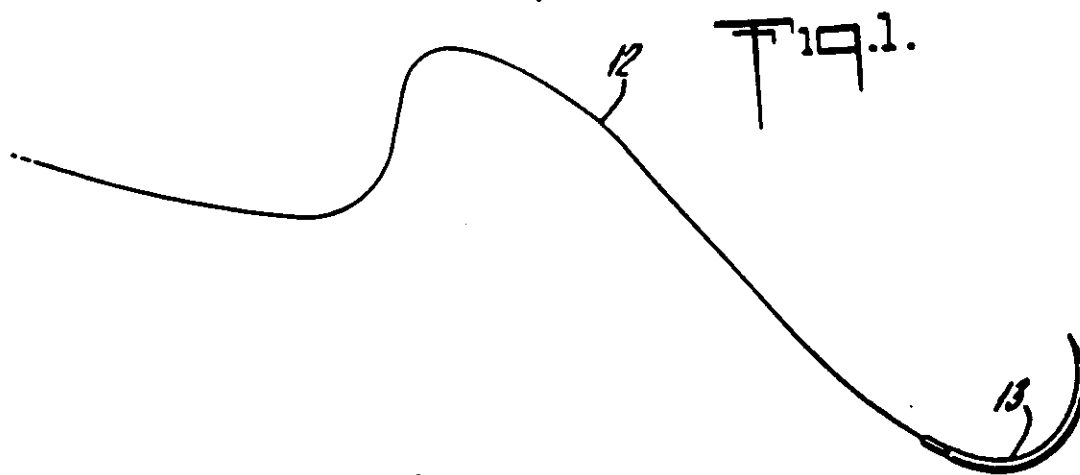
Synthetic absorbable sutures are prepared from copolyoxalate polymers having isomorphic sequences. The polymers are derived from mixtures of cyclic and linear diols, each having the same carbon chain length of 6 or 8 atoms. The cyclic diol may be aliphatic or aromatic. The diols are polymerized with dialkyl oxalate, preferably in the presence of an inorganic or organometallic catalyst, to obtain a highly crystalline isomorphic copolyoxalate polymer which is melt extruded and drawn to form oriented filaments. The filaments are characterized by good initial tensile and knot strength and a high order of softness and flexibility. When implanted in living animal tissue, the fibers have good strength retention over a period of at least 21 days and eventually absorb with a minimal degree of adverse tissue reaction.

21 Claims, 5 Drawing Figures



DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS

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ISOMORPHIC COPOLYOXALATES AND SUTURES THEREOF

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to synthetic absorbable sutures, and more particularly, to synthetic absorbable sutures comprising extruded and oriented filaments of copolymers of polyoxalates having isomorphic sequences.

2. Description of Prior Art

Absorbable suture materials have traditionally been natural collagenous materials obtained from sheep or beef intestine, commonly known as catgut. More recently, it has been proposed to manufacture synthetic absorbable sutures from: polyesters of hydroxycarboxylic acids, notably polylactide, polyglycolide, and copolymers of lactide and glycolide. Such synthetic absorbable sutures are described in U.S. Pat. Nos. 3,636,956, 3,297,033 and elsewhere in the literature. Polyesters of succinic acid have also been suggested for at least partially bioresorbable surgical articles as disclosed for example in U.S. Pat. No. 3,883,901.

Among the requirements of an ideal absorbable suture are that it should have good handling properties, should approximate and hold tissue for proper healing with minimal tearing and tissue damage, should have adequate straight tensile and knot strength, should be controllably uniform in properties including dimensional stability within the body, should be sterilizable, should be absorbable by living tissue, preferably at a constant rate regardless of the place in the body or the condition of the patient and without causing such unfavorable tissue reactions as walling off, granuloma formation or excessive edema, and finally should be capable of being properly and easily tied into surgical knots.

While multifilament sutures manufactured from polymers of lactide and glycolide fulfill the above requirements to a large degree, monofilament sutures of these materials are considerably less flexible than catgut and these synthetic sutures are accordingly generally limited to a multifilament, braided construction. Sutures of glycolide polymers are also not suitable for sterilization by radiation without suffering severe degradation of physical properties.

We have discovered that copolyoxalate copolymers having isomorphic sequences can be melt extruded into pliable, monofilament fibers which have good in vivo strength retention and are absorbed in animal tissue without significant adverse tissue reaction. The fibers have good tensile and knot strength, and can be sterilized by gamma radiation without serious loss of these properties. In addition, monofilament sutures of the polymers of the present invention have a high degree of softness and flexibility not found in many synthetic absorbable sutures of the prior art.

The preparation of polyoxalate polymers is described in the art. Carothers et al., J. Amer. Chem. Soc. 52, 3292 (1930) for example, describes the ester interchange reaction of diols such as ethylene glycol, 1,3-propanediol, or 1,4-butanediol with diethyl oxalate to yield a mixture of monomer, soluble polymer and insoluble polymer. The reaction of oxalic acid and an alkylene glycol to form polyester resins is described in U.S. Pat. No. 2,111,762, while the preparation of polyesters of fiber-forming quality from dicarboxylic acids and diols is described in U.S. Pat. Nos. 2,071,250-1 and 2,952,652. Isomorphic polymers including polyester copolymers have been

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discussed in the literature⁽¹⁾. The particular isomorphic copolyoxalates of the present invention however, have not previously been known, nor has their preparation or use as synthetic absorbable sutures been suggested heretofore.

It is accordingly an object of the present invention to provide new and useful polymers of isomorphic copolyoxalates and articles made therefrom. A further object of this invention is to provide synthetic absorbable sutures of isomorphic copolyoxalates. It is a yet further object of this invention to provide surgical aids and prostheses fabricated of fibers or cast or machined from blocks of isomorphic copolyoxalate polymers.

SUMMARY

Highly crystalline isomorphic polyoxalate polymers are prepared by reacting mixtures of cyclic and linear diols with dialkyl oxalate, preferably in the presence of an inorganic or organometallic catalyst. The diols comprising the reaction mixture have the same carbon chain length separation between terminal OH groups of 6 or 8 carbon atoms. The cyclic diol may be trans 1,4-cyclohexane dialkanol or p-phenylene dialkanol and comprises

(1) Isomorphism in Synthetic Macromolecular Systems, G. Allegra and I. W. Bassi, Adv. Polymer Sci. 6, 549 (1969) from about 5 to 95 mol percent, and preferably from 40 to 75 mol percent of the total diol reactant.

Copolymers prepared by the transesterification reaction of the two diols and diethyl oxalate are melt extruded into highly crystalline filaments suitable for use as synthetic absorbable sutures. Drawn and oriented filaments are characterized by high tensile and knot strength, a Young's modulus in most cases of less than about 600,000 psi providing a high order of filament softness and flexibility, and good strength retention and minimal tissue reaction in vivo.

DESCRIPTION OF DRAWINGS

FIG. 1 is a perspective view of a needle-suture combination;

FIG. 2 is a perspective view of a needle-suture combination within a hermetically sealed container;

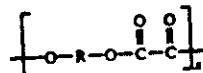
FIG. 3 illustrates a screw machined from the polymer of the present invention;

FIG. 4 is a cross-sectional view of a composite yarn containing filaments of different composition and;

FIG. 5 is a plan view of a surgical fabric knitted from fibers of the present invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

Polymers of the present invention are comprised of isomorphic units of cyclic and linear oxalates and have the general formula



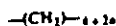
wherein each R is



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with from about 5 to 95 mol percent, and preferably from about 40 to 75 mol percent of R groups being I; A is trans 1,4-cyclohexylene or p-phenylene, a is 1 or 2 and is the same for I and II, and x is the degree of polymerization resulting in a fiber forming polymer having a molecular weight greater than about 10,000.

Polymers of the present invention are conveniently prepared by an ester interchange reaction between the afore-described mixture of diols and a lower ester of oxalic acid, preferably in the presence of an ester interchange catalyst. The preferred ester of oxalic acid is diethyl oxalate. The ester interchange is most preferably conducted in two stages wherein the reactants are first heated with stirring under a nitrogen atmosphere to form a prepolymer with the removal of ethanol, followed by postpolymerization under heat and reduced pressure to obtain a final polymer of the desired molecular weight and fiber forming quality. Polymers with low or moderate degrees of polymerization are postpolymerized in the liquid state or as finely-divided solid particles, depending on their melting temperature range.

The polymer is melt extruded through a spinnerette in a conventional manner to form one or more filaments which are subsequently drawn about 4X to 6X in order to achieve molecular orientation and improve tensile properties. The resulting oriented filaments have good tensile and dry knot strength and good in vivo strength retention.

It is well documented that the crystallinity and hence suitability for fiber-formation in both the AB and AA-BB type polyesters decreases significantly when the mol fraction of the major comonomer sequence decreases below about 80%. In some instances, if the comonomer sequences are isomorphous, chains composed of slightly less than 80% of the major sequences can pack into a crystalline form. However, randomly constructed copolyester chains based on almost equal amounts of the isomorphous comonomer sequences are generally found to be non-crystalline and poor fiber formers. Contrary to this general rule, the isomorphous copolyesters of the present invention display an unexpectedly high level of crystallinity of about 45% in a 50/50 copolyester. The polymers of the present invention are also unusual in that all copolymers through the entire composition range of from 5 to 95% of each isomorphous comonomer demonstrate levels of crystallinity comparable to those encountered in the parent homopolymers; namely between 30 and 50% depending on the thermal history. A similarly striking observation characteristic of these copolyesters is their display of melting endotherms, as shown by DSC, for the crystalline regions of all copolymers within the composition range of from about 5 and 95 mol % of each isomorphous comonomer. Constructed curves of the melting temperature versus composition did not reveal any positive eutectic composition in these systems. The X-ray and DSC data suggest strongly the uncommon presence of almost complete isomorphism in the copolyesters of the present invention.

Dimensional stability and tensile strength retention of the oriented filaments may be enhanced by subjecting the filaments to an annealing treatment. This optional treatment consists of heating the drawn filaments to a temperature of from about 40° to 130° C., most preferably from about 60° to 110° C. while restraining the filaments to prevent any substantial shrinkage. The filaments are held at the annealing temperature for a

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few seconds to several days or longer depending on the temperature and processing conditions. In general, annealing at 60° to 110° C. for up to about 24 hours is satisfactory for the polymers of the present invention. Optimum annealing time and temperature for maximum fiber in vivo strength retention and dimensional stability is readily determined by simple experimentation for each fiber composition.

Filaments of the present invention may be used as sutures in either a monofilament or a multifilament construction. Multifilament sutures are preferably braided but may also be twisted or covered in accordance with common practice. For use as sutures, it is necessary that the fibers be sterile, and sterilization may be accomplished by exposing the fibers to Cobalt 60 gamma radiation or to ethylene oxide. Such sterilization techniques are well known and commonly practiced in suture manufacture.

Since the function of a suture is to join and hold severed tissue until healing is well along, and to prevent wound separation as a result of movement or exercise, a suture must meet certain minimum standards of strength. It is particularly important that strength be maintained when knots are tied and during the actual procedure of drawing tight a suitable knot. Sutures prepared from oriented filaments of the present invention are characterized by a straight tensile strength of at least about 30,000 psi and a knot strength of at least about 20,000 psi, although significantly higher strengths may be obtained.

The preparation of high molecular weight oriented filaments of isomorphous polyoxalates is further illustrated by the following examples where all percentages are on a molar basis unless otherwise noted. The following analytical methods were used to obtain the data reported in the examples. Inherent viscosity (η_{inh}) was obtained on polymer solutions (1 gram/liter) in chloroform or hexafluoro-2-propanol (HFIP). The infrared spectra of polymer films (cast from $CHCl_3$ or HFIP) were recorded on a Beckman Acculab 1 spectrophotometer. The NMR spectra of the polymer solutions in $CHCl_3$ were recorded on an MH-100 or CFT-20 spectrophotometer. A DuPont 990 DSC apparatus was used to record the glass transition (T_g), crystallization (T_c) and melting (T_m) temperatures of the polymers under nitrogen, using about 5 mg samples and a heating rate of 10° C./min. or as otherwise specified. The thermogravimetric analysis (TGA) data of the polymers were recorded under nitrogen using a DuPont 950 TGA apparatus and a heating rate of 10° or 20° C./min. with about 10 mg samples. A Phillips vertical goniometer with graphite crystal monochromatized copper K_α radiation was used to obtain the X-ray powder and fiber diffraction patterns of the polymers. Crystallinity was determined by the method of Hermans and Weidinger and the diffractometer patterns were resolved with a DuPont 310 curve analyzer.

In vitro hydrolysis of polymer discs (about 1.2 g, 2.2 cm diameter) and monofilaments (7-25 mil) was conducted at 37° C. in phosphate buffer comprising a solution of 27.6 g sodium dihydrogenphosphate monohydrate in 1000 ml. water adjusted to pH 7.25 with sodium hydroxide.

In vivo absorption (muscle) was determined by implanting two 2 cm segments of monofilament fiber into the left gluteal muscles of female Long Evans rats. The implant sites were recovered after periods of 60, 90, 120

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180 days and examined microscopically to determine the extent of absorption. In vivo absorption (subcutaneous) is a non-histological technique in which continuous observation of the biological degradation of segments of suture is made by implanting two segments of suture, 2 cm long, into the abdominal subcutis of a female rat. The implants are readily visible on the skin and are wetted with propylene glycol and the extent of absorption can be determined by subjective examination.

In vivo strength retention was determined by implanting segments of sutures in the posterior dorsal subcutis of female Long Evans rats for period of 5 to 30 days. The sutures were recovered at the designated periods and pull-tested for straight tensile strength. In vitro strength retention was determined by placing segments of sutures in the afore-defined buffer at 50° C. for periods of 2 to 4 days. The sutures were recovered at the designated periods and pull-tested for straight tensile strength.

EXAMPLES

General Polymerization Procedure

Diethyl oxalate was heated with selected diols in a mechanically-stirred reactor using a stannous alkanoate organic titanate catalyst. The reaction was conducted under a nitrogen atmosphere at suitable temperatures until a substantial portion of the calculated amount of ethanol was obtained. Postpolymerization of the resulting prepolymer was then continued under reduced pressure using a suitable heating scheme. At the end of the postpolymerization period, the molten polymer was allowed to cool slowly at room temperature, isolated, ground and dried at 25° C. to 80° C. (depending on the polymer T_m) in vacuo for at least one day. Alternatively, the prepolymer can be postpolymerized partially in the liquid state, cooled, and then postpolymerized further in the solid state as finely divided particles. Detailed experimental conditions for the preparation of representative samples of isomeric polyoxalates and important properties of the resulting polymers are presented below.

EXAMPLE I

95/5 Poly (trans 1,4-Cyclohexylenedicarbinyl-co-hexamethylene Oxalate)

Distilled diethyl oxalate (19.0 g, 0.130 mol), recrystallized trans 1,4-cyclohexanedimethanol (19.8 g, 0.137 mol), 1,6-hexadiol (0.856 g, 0.00724 mol) and stannous octoate (0.33 M in toluene; 0.080 ml, 0.026 mmol) were added under dry and oxygen-free conditions to a glass reactor equipped for magnetic stirring. The prepolymer was formed by heating the mixture at 120° C. for 3 hours under nitrogen at 1 atmosphere while allowing the formed ethanol to distill, followed by heating at 60° C. for 2 hours. The prepolymer was then heated in vacuo (0.05 mm Hg) at 220° C. for 1 hour, and the postpolymerization completed by heating at 215° C. for an additional 6 hours. The polymer was then allowed to cool to room temperature, isolated and ground, and finally dried in vacuo at room temperature.

Polymer Characterization:

η_{inh} in $CHCl_3$ = 0.50

DSC (20° C./min.): T_m = 210° C.

Polymer Melt-Spinning:

The polymer was spun using an Instron Rheometer with a 30 mil die at 207° C.

In Vitro Evaluation:

The undrawn fibers lost 21 and 66 percent of their initial mass after immersion in phosphate buffer at 37° C. for 42 and 127 days, respectively.

EXAMPLE II

85/15 Poly (1,4-Cyclohexylenedicarbinyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (58.4 g, 0.400 mols), recrystallized trans 1,4-cyclohexanedimethanol (less than 1% cis isomer; 53.9 g, 0.374 mols), 1,6-hexanediol (7.8 g, 0.066 mol), and stannous octoate (0.33M in toluene; 0.40 ml, 0.13 mmol) were added under dry and oxygen-free conditions to a glass reactor equipped for mechanical stirring. The mixture was heated at 120° and 150° C. for 2 and 3 hours, respectively, under nitrogen at one atmosphere while the formed ethanol distilled. The prepolymer was allowed to cool, then reheated to 200° C. under reduced pressure (0.1 mm Hg). Temperatures of 200°, 220° and 230° C. were maintained for 2, 3 and 4 hours while the collection of distillates continued. The resulting polymer (η_{inh} in $CHCl_3$ = 0.49) was cooled, isolated, ground (2 mm screen size), and then dried in vacuo at room temperature. Portions (30 g) of this ground polymer were postpolymerized in the solid state in glass reactors equipped for magnetic stirring by heating in vacuo (0.1 mm Hg) at 185° C. for 22 hours.

Polymer-Characterization:

η_{inh} in $CHCl_3$ = 1.14

DSC (20° C./min.): T_m = 187° C.

Polymer Melt-Spinning:

The polymer was spun at 230° C. using an Instron Rheometer with a 40 mil die. The fiber was quenched in ice water, wound, dried and subsequently drawn.

Fiber Properties:

Fibers drawn 5X in two stages, 4X at 62° C. followed by 1.25X at 119° C. exhibited the following properties: diameter = 8.5 mils, straight tensile strength = 8.39×10^4 psi; knot tensile strength = 5.06×10^4 psi; modulus = 6.61×10^5 psi; elongation = 15%.

In Vivo Evaluation:

Sterilized (via γ -radiation, 2.5 Mrads), drawn monofilament (8.5 mils) retained 89, 75, 10 and zero percent of its initial breaking strength (4.8 lbs.) after subcutaneous implantation in rat muscle for 3, 7, 14 and 21 days respectively. Drawn filaments implanted into the gluteal muscles of rats elicited median tissue responses in the slight range throughout a 180 day post-implantation period. Filaments drawn 4X at 60° C. followed by 1.25X at 110° C. and having a straight tensile of 6.76×10^4 psi showed indications of initial degradation 20 to 26 weeks after implantation.

In Vitro Evaluation:

Fibers drawn 4X at 60° C. (exhibiting a straight tensile of 4.33×10^4 psi) lost 40 percent of their initial mass after immersion in phosphate buffer at 37° C. for 84 days.

EXAMPLE III

80/20 Poly (1,4-Cyclohexylenedicarbinyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (43.8 g, 0.300 mol), recrystallized trans 1,4-cyclohexanedimethanol (cis isomer con-

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tent = 1.0%, 36.3 g, 0.252 mol), 1,6-hexanediol (7.4 g, 0.063 mol), and stannous oxalate (12.4 mg, 0.060 mmol) were added under dry and oxygen-free conditions to a glass reactor equipped for mechanical stirring. The prepolymer was formed by heating the mixture at 120° C. for 2 hours under nitrogen at 1 atmosphere while allowing the formed ethanol to distill, followed by 160° C. for 2.5 hours. The mixture was allowed to cool, then reheated in vacuo (0.1 mm Hg) to 140° C. and maintained until the prepolymer melted. The temperature was then increased to 190° C., maintained for 30 minutes, then raised to 200° C. for 1.5 hours. The melt post-polymerization of the stirred polymer was completed by heating at 220° C. for 4.5 hours. The polymer was cooled, isolated, ground (screen size = 2 mm) and dried in vacuo at room temperature. To obtain the final product, the ground polymer was post-polymerized in the solid state in a glass reactor equipped for magnetic stirring by heating at 180° C. in vacuo (0.05 mm Hg) for 24 hours while allowing the formed diols to distill.

Polymer Characterization:

η_{inh} in $CHCl_3$ = 1.33

DSC (20° C./min.): T_m = 205° C.

Polymer Melt-Spinning:

The polymer was spun at 240° C. using an Instron Rheometer equipped with a 40 mil die. The extruded filaments were quenched in ice water, wound, then dried at room temperature in vacuo, and subsequently drawn 4X.

Fiber Properties:

Diameter = 9.0 mils; straight tensile strength = 7.31×10^4 psi; knot tensile strength = 3.46×10^4 psi; modulus = 7.7×10^3 psi; elongation = 15%.

In Vivo Evaluation:

Sterilized (by γ -radiation, 2.5 Mrads), fibers (9.0 mil) retained 85, 20 and zero percent of their initial breaking strength (4.2 lbs.) after subcutaneous implantation in rat muscles for 3, 7 and 14 days, respectively. These fibers were also implanted into the gluteal muscles of rats to determine tissue response and absorption characteristics. The median tissue response elicited by the samples was in the slight range after 5 days post implantation and in the minimal range after 42 days; absorption of the samples was first noted at 120 days and by 180 days approximately fifty percent of the material had been absorbed.

EXAMPLE IV

80/20 Poly

(1,4-Cyclohexylenedicarbonyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (23.4 g, 0.160 mol), recrystallized trans 1,4-cyclohexanedimethanol (cis isomer content = 6.3%; 20.0 g, 0.139 mol), 1,6-hexanediol (4.1 g, 0.035 mol) and Tyzor OG® (0.117M in toluene, 0.28 ml, 0.033 mmols) were added under dry and oxygen-free conditions to a glass reactor equipped for magnetic stirring. A prepolymer was formed by heating the mixture at 120° C. for 19 hours under nitrogen at 1 atmosphere while allowing the formed ethanol to distill. The pressure was then reduced (0.05 mm Hg) and heating at 120° C. continued for 30 minutes longer. The temperature was then increased and maintained at 180° C., 190° C. and 200° C. for 2, 5 and 2 hours, respectively, while removing excess and formed diols. The polymer was allowed to cool, isolated, ground, and dried in vacuo at room temperature.

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*Tyzor OG, a titanium glycolate catalyst manufactured by E. I. Du Pont de Nemours and Co., Wilmington, Del., 1999

Polymer Characterization:

η_{inh} in $CHCl_3$ = 0.46

DSC (10° C./min.): T_m = 171° C.

TGA (10° C./min. under N_2): 0.25% weight lost at 275° C.

Polymer Melt-Spinning:

The polymer was spun using an Instron Rheometer with a 30 mil die at 172° C. The extruded filaments were quenched in ice water, dried in vacuo at room temperature, and finally drawn 5X at 43° C.

Fiber Properties:

η_{inh} in $CHCl_3$ = 0.42

X-ray: Major reflections correspond to 8.9 (W), 4.84 (M), 4.41 (S) and 3.42 Å (W) d-spacings; 26% crystallinity. (Undrawn filaments were found to be 22% crystalline which increased to 31% by annealing at 70° C. for one hour).

Physical Properties:

Diameter = 11.1 mils; straight tensile strength = 2.07×10^4 psi; elongation = 35%.

In Vivo Evaluation:

The rate of absorption and tissue response of drawn filaments was determined by implantation into the ventral abdominal subcutis of Long-Evans rats. Some evidence of filament degradation was noted 11 to 14 weeks after implantation, with the bulk of the fiber being absorbed by 20 to 23 weeks. No tissue reaction to the implants was noted at any period.

In Vitro Evaluation:

The drawn fibers exhibited a 43% decrease in mass after immersion in the phosphate buffer at 37° C. for 28 days.

EXAMPLE V

67/33 Poly(trans

1,4-cyclohexylenedicarbonyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (40.0 g, 0.274 mol), recrystallized trans 1,4-cyclohexanedimethanol (25.9 g, 0.180 mol), 1,6-hexanediol (10.6 g, 0.0897 mol), and stannous octoate (0.33 M in toluene; 0.16 ml, 0.053 mmol) was added to a glass reactor equipped for mechanical stirring. The prepolymer was formed by heating the mixture under nitrogen at 120° C. for 9 hours, followed by 125° C. for 9 hours while collecting the distillates. The prepolymer was cooled, then reheated in vacuo (0.03 mm Hg) and maintained at 80, 120, 150, 170 and 180° C. for 1, 2, 2, 3 and 1.5 hours, respectively. The postpolymerization of the polymer melt was completed by heating at 195° C. for 6 hours while continuing to stir and remove distillates. The polymer was cooled, isolated, ground, and then dried at room temperature.

Polymer Characterization:

η_{inh} in $CHCl_3$ = 0.49

DSC (20° C./min.): T_m = 179° C.

Polymer Melt Spinning:

The polymer was spun at 175° C. using an Instron Rheometer with a 30 mil die. The resulting fibers were subsequently drawn 4X at 50° C.

Fiber Properties:

Diameter = 9.3 mils, straight tensile strength = 2.65×10^4 psi, knot tensile strength = 2.21×10^4 psi, modulus = 3.7×10^3 psi.

In Vivo Evaluation, Tissue Reaction:

Two centimeter long samples of sterilized (by γ -radiation, 2.5 Mrads) drawn fiber were implanted sub-

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cutaneously in the abdominal wall of young female Long Evans strain rats. At intervals of 3, 14, 28, 56 and 90 days, two rats were sacrificed for examination of implants. The skin containing the fibers was excised and affixed to plastic sheets for preservation in formalin. Two tissue blocks were cut transversely from each site and embedded in paraffin for histologic preparation. Eight stained samples were examined at each interval for tissue reaction to the fibers. Only mild foreign body reactions were detected.

In Vivo Evaluation, Absorption:

Fiber segments sterilized by γ -radiation (2.5 Mrads) approximately 2 cm in length were inserted into the ventral abdominal subcutis of Long Evans rats (100 g. female) to determine the rate of absorption of the drawn fibers. One to two rats were sacrificed after various periods after implantation. The skin containing the implant sites was removed and dried. These preparations were examined and evaluated using both dissecting and transmission microscopes. Estimates of the amount of implant remaining were based on the length of the segment or fragments remaining and the decrease in the surface area made by palpating the implant in the dried hide and comparing it with a one week old preparation. Implants were fragmented at one week; migration and clumping of fragments was noted at subsequent kill periods. Evidence of degradation was first seen 16 weeks after implantation. Palpable fragments, in diminishing amounts, were present until 30 weeks. Quantitatively, about 100, 75, 45, 40, 20, 15 and 5 or less percent of the suture remained after 14, 16, 20, 23, 26, 30 and 36 weeks.

EXAMPLE VI

50/50 Poly (trans

1,4-cyclohexyldicarbonyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (38.0 g, 0.260 mol), recrystallized trans 1,4-cyclohexanedimethanol (20.2 g, 0.140 mol), 1,6-hexanediol (16.5 g, 0.140 mol), and stannous octoate (0.33 M in toluene, 0.16 ml, 0.053 mmol) were added under dry and oxygen-free conditions to a mechanically stirred glass reactor. Under nitrogen at one atmosphere, the mixture was heated to and maintained at 120° C. for 20 hours, while allowing the formed ethanol to distill. The prepolymer was cooled and then reheated in vacuo (0.05 mm Hg) to and maintained at 80°, 120°, 140°, 165°, 175°, 185°, and 195° C. for 1, 1, 3, 3.5, 2, 1 and 1 hour respectively. The removal of the diols was continued by heating at 200° C. for 8 hours to complete the postpolymerization. The polymer was cooled, isolated, ground, and then dried in vacuo at room temperature.

Polymer Characterization:

η_{inh} in $CHCl_3$ = 0.36

DSC (20° C./min.): T_m = 138° C.

Polymer Melt Spinning:

The polymer was spun at 136° C. using an Instron Rheometer (40 mil die) and was immediately drawn 5X at 53° C.

Fiber Properties:

X-ray Data: Major reflections correspond to 8.9 (W), 4.84 (M), 4.41 (S), and 3.40 Å (W) d-spacings; 36% crystallinity.

Physical Properties: Diameter = 10.6 mils, straight tensile strength = 1.36×10^4 psi, knot tensile strength = 1.13×10^4 psi, modulus = 1.33×10^5 psi, elongation = 27%.

In Vivo Evaluation:

Sterilized (by γ -radiation) drawn fiber segments (2 centimeters in length) were implanted into the ventral abdominal subcutis for study of the rate of absorption and tissue reaction.

At one week the implants were fragmented, clumping, and migrating, with the bulk of the suture being absorbed between 6 to 11 weeks. Thereafter, fragments with scattered birefringent particles or birefringent particles in a shell-like outline were observed. The birefringent particles decreased in amount until at 36 weeks only a few widely scattered particles were noted.

Only mild foreign body reactions were observed to be elicited by the sterilized drawn fiber segments during the test intervals of 3, 14, 28, 48, 90 and 180 day post implantation.

In Vitro Evaluation:

Undrawn fibers exhibited a 57 percent decrease in their initial mass after immersion in phosphate buffer at 37° C. for 28 days.

EXAMPLE VII

50/50 Poly (trans

1,4-cyclohexyldicarbonyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (58.5 g, 0.400 mol), recrystallized trans 1,4-cyclohexanedimethanol (cis isomer content = 0.7%; 29.7 g, 0.206 mol), 1,6-hexanediol (24.3 g, 0.206 mol), and stannous octoate (16.5 mg, 0.080 mmols), were added under dry and oxygen-free conditions to a mechanically stirred glass reactor. The mixture was heated under nitrogen at one atmosphere to and maintained at 120° and 160° C. for 3 and 2 hours respectively while allowing the formed ethanol to distill. The prepolymer was cooled and then reheated in vacuo (0.05 mm Hg) and maintained at 170°, 190° and 205° C. for 3, 2.5 and 3 hours respectively while continuing to remove excess and formed diol to complete the postpolymerization. The polymer was cooled, isolated, ground, and then dried in vacuo at room temperature.

Polymer Characterization:

η_{inh} in HFIP = 1.07

DSC (20° C./min.) T_m = 132° C.

Polymer Melt Spinning:

The polymer was spun at 150° C. using an Instron Rheometer (40 mil die) and was drawn 4X at 50° C. followed by 1.5X at 72° C.

Fiber Properties:

X-ray Data: Major reflections correspond to 9.11 (MS), 4.82 (S), 4.60 (W), 4.37 (S) and 3.45 Å (W) d-spacings; 46% crystallinity.

Physical Properties: Diameter = 7.6 straight tensile strength = 51,300 psi, knot tensile strength = 36,400 psi, elongation = 31%.

EXAMPLE VIII

30/70 Poly (trans

1,4-cyclohexylenedicarbonyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (36.5 g, 0.250 mol), recrystallized trans 1,4-cyclohexanedimethanol (11.5 g, 0.0797 mol), 1,6 hexanediol (22.4 g, 0.190 mol), and stannous octoate (0.33 M in toluene; 0.16 ml, 0.053 mmol) were added under dry and oxygen-free conditions to a mechanically stirred reactor. The mixture was heated to and maintained at 125°, 140° and 160° C. for 2, 2 and 1 hour, respectively, under nitrogen at one atmosphere

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while allowing the formed ethanol to distill. The prepolymer was cooled and then reheated in vacuo (0.1 mm Hg) and maintained at 150° and 185° C. for 16 and 3 hours, respectively. The postpolymerization was completed by maintaining the polymer at 200° C. for 5.5 hours while continuing to remove the diols under vacuum. The polymer was then cooled, isolated, ground and dried in vacuo at room temperature.

Polymer Characterization:

η_{inh} in $CHCl_3$ = 0.82

DSC (20° C./min): T_m = 85° C.

Polymer Melt Spinning:

The polymer was spun at 125° C. using an Instron Rheometer with a 40 mil die. The fiber was quenched in ice water, wound, dried in vacuo at room temperature, and subsequently drawn 5.6X at room temperature, followed by annealing at 55° C.

Fiber Properties:

Diameter 8.3 mils, straight tensile strength 5.18×10^4 psi, knot tensile strength 3.51×10^4 psi, modulus 2.11×10^5 and elongation 50%.

In Vivo Evaluation:

Sterilized (by γ -radiation, 2.5 Mrads), drawn fibers (9.8 mil diameter; 3.64×10^4 psi straight tensile strength; 2.34×10^4 psi knot tensile strength; 1.47×10^5 psi modulus; and an elongation of 45%) were implanted into the gluteal muscles of rats to determine their absorption and tissue response characteristics at 5, 21, 42 and 150 days post implantation.

At the 42 day period, there was no evidence of any morphologic changes of the implant sites indicating absorption. At the 150 day period, the fibers had a median value of 2 percent suture cross sectional area remaining (with a range of 0 to 20 percent).

Foreign body tissue responses to the samples were in the slight range at 5, 21 and 42 day periods and in the minimal range at the 150 day period.

In Vitro Evaluation:

Drawn fibers possessing physical properties similar to those of fibers used in the in vivo testing exhibited a 100% decrease in their initial mass after 141 days of immersion in phosphate buffer at 37° C.

EXAMPLE IX

5/95 Poly (trans
1,4-cyclohexylenedicarbonyl-co-hexamethylene
Oxalate):

Distilled diethyl oxalate (19.0 g, 0.130 mol), recrystallized trans 1,4-cyclohexanedimethanol (1.0 g, 0.0069 mol), 1,6-hexanediol (16.3 g, 0.138 mol), and stannous octoate (0.33 M in toluene; 0.08 ml, 0.026 mmol) were added under dry and oxygen-free conditions to a glass reactor equipped for magnetic stirring. The prepolymer was formed by heating the mixture at 120° C. for 3 hours under nitrogen at one atmosphere while allowing the formed ethanol to distill, followed by 160° C. for 2 hours. The prepolymer was heated and maintained at 205° C. for 8 hours in vacuo (0.05 mm Hg). The polymer was then cooled, isolated, ground, and dried at room temperature.

Polymer Characterization:

η_{inh} in $CHCl_3$ = 0.88

DSC (20° C./min): T_m = 69° C.

TOA (20° C./min. under N_2): Less than 0.5% weight loss at 275° C. was recorded.

Polymer Melt Spinning:

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The polymer was spun in an Instron Rheometer using 30 mil die at 85° C. The fibers were quenched in ice water and subsequently drawn 5X at room temperature.

Fiber Properties:

Diameter = 14.7 mils, straight tensile strength = 1.36×10^4 psi, knot tensile strength = 1.41×10^4 psi, modulus = 4.8×10^4 psi, elongation = 90%.

In Vitro Evaluation:

The drawn fibers exhibited a 93 percent decrease in their initial mass after immersion in phosphate buffer at 37° C. for 42 days.

EXAMPLE X

58/42 Poly (1,4-phenylenedicarbonyl-co-hexamethylene
Oxalate):

Diethyl oxalate (14.6 g, 0.100 mols), recrystallized 1,4-benzenedimethanol (6.9 g, 0.050 mols), 1,6-hexanediol (8.3 g, 0.070 mols), and Tyzor TOT[®] catalyst (0.4 ml of a 1% solution) were added under dry and oxygen-free conditions to a glass reactor equipped for stirring. The prepolymer was formed by heating under nitrogen at one atmosphere at 140° C. for 4 hours while allowing the formed ethanol to distill. The mixture was then heated in vacuo (0.1 mm Hg) at 165° C. for 22 hours while continuing to remove distillates. A postpolymerization was conducted at 180°, 190°, and 200° C. for 2, 1 and 4 hours respectively. The polymer was cooled, ground and dried.

[®]Tyzor TOT, a tetraalkyl titanate catalyst manufactured by E. I. Du Pont de Nemours and Co., Wilmington, Delaware, 19898.

Polymer Characterization:

η_{inh} in HFIP = 0.48

DSC (10° C./min): T_m = 170° C.

TOA (10° C./min in N_2): Less than 1% cumulative weight loss experienced at 250° C.

Polymer Melt Spinning:

The polymer was spun at 166° C. using an Instron Rheometer equipped with a 30 mil die.

In Vitro Evaluation:

Immersion of a molded disc, 2.2 cm in diameter, for 8 and 78 days in phosphate buffer at 37° C. resulted in a loss of 3 and 99 percent of the initial mass, respectively.

EXAMPLE XI

45 56/44 Poly (1,4-phenylenedicarbonyl-co-hexamethylene
Oxalate):

Dibutyl oxalate (20.2 g, 0.100 mols), 1,4-benzenedimethanol (8.3 g, 0.060 mols), 1,6-hexanediol (5.6 g, 0.047 mols), and tetraisopropylorthotitanate catalyst (0.3 ml, of a 0.01M solution) were added under dry and oxygen-free conditions to a glass reactor equipped for magnetic stirring. The prepolymer was formed by heating at 140°, and 160° C. for 1, and 17 hours respectively under nitrogen at one atmosphere while allowing the formed butanol to distill. The pressure was reduced (0.2 mm Hg) while continuing to heat at 160° C. for an additional hour. The postpolymerization of the polymer melt was completed by heating at 180° C. and 200° C. for 2, and 3.5 hours, respectively, while continuing to remove distillates. The polymer was cooled, and isolated.

Polymer Characterization:

η_{inh} in HFIP = 0.42

DSC (10° C./min): T_m = 165° C.

TOA (10° C./min in N_2): Less than 1% cumulative weight loss experienced at 250° C.

In Vitro Evaluation:

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Immersion of a molded disc, 2.2 cm in diameter, for 7 and 77 days, in phosphate buffer at 37° C. resulted in a loss of 3 and 36 percent of the initial mass, respectively.

EXAMPLE XII

50/50 Poly (1,4-phenylenedicarbinyl-co-hexamethylene Oxalate):

In a manner similar to that employed in Examples X and XI, the above identified copolymer having the following characteristics was produced:

DSC (10° C./min): $T_m = 175^\circ \text{C}$.

TOA (10° C./min, in N_2): Less than 1% cumulative weight loss experienced at 250° C.

In Vitro Evaluation:

Immersion of a molded disc, 2.2 cm in diameter, for 8 and 78 days in phosphate buffer at 37° C. resulted in a loss of 6 and 34 percent of the initial mass, respectively.

While the preceding examples have been directed to the preparation of specific copolymers of polyoxalates, these examples are for purposes of illustration only and are not limiting of the invention. Mixtures of these polymers and combinations of these polymers with up to about 50 percent by weight of poly (alkylene oxalates) and other compatible polymers which produce non-toxic and absorbable polymers are likewise included within the present invention.

It is to be understood that inert additives such as coloring materials and plasticizers can be incorporated in the sutures. As used herein, the term "inert" means materials that are chemically inert to the polymer and biologically inert to living tissue, i.e., do not cause any of the adverse effects previously discussed. Any of a variety of plasticizers such as, for instance, glyceryl triacetate, ethyl benzoate, diethyl phthalate, dibutyl phthalate and bis-2-methoxyethyl phthalate can be used if desired. The amount of plasticizer may vary from 1 to about 20 percent or more based on the weight of the polymer. Not only does the plasticizer render the filaments of the present invention even more pliable, it also serves as a processing aid in extrusion and thread preparation.

Filaments of the present invention are adversely affected by moisture and are accordingly preferably stored in hermetically sealed and substantially moisture-free packages, a preferred form of which is shown in FIG. 4. In FIG. 2, there is shown a suture package 14 having disposed therein a coil of suture 12, one end of which is attached to needle 13. The needle and suture are positioned within a cavity 16 that is evacuated or filled with a dry atmosphere of air or nitrogen. The illustrated package is fabricated of two sheets of aluminum foil or an aluminum foil-plastic laminate and heat sealed or bonded with adhesive at the skirt 16 to hermetically seal the cavity and isolate the contents of the package from the external atmosphere.

Filaments of the present invention may be used as monofilament or multifilament sutures, or may be woven, braided, or knitted either alone or in combination with other absorbable fibers such as poly (alkylene oxalate), polyglycolide or poly (lactide-co-glycolide), or with nonabsorbable fibers such as nylon, polypropylene, polyethylene-terephthalate, or polytetrafluoroethylene to form multifilament sutures and tubular structures having use in the surgical repair of arteries, veins, ducts, esophagi and the like.

Multifilament yarns that contain isomorphous polyoxalate filaments of the present invention together with nonabsorbable filaments are illustrated in FIG. 4

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wherein the nonabsorbable fiber is represented by the hatched fiber cross-section 19. In FIG. 4, the fibers 20 are extruded from polymer compositions of the present invention as described above. The relative proportions of absorbable filaments 20 and nonabsorbable filaments 19 may be varied to obtain the absorption characteristic desired in the woven fabric or tubular implants.

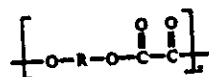
Composite fabrics of absorbable and nonabsorbable materials fashioned by textile processes including weaving, knitting and nonwoven felting are described in U.S. Pat. Nos. 3,108,357 and 3,463,158. Methods of weaving and crimping tubular vascular prostheses are described in U.S. Pat. No. 3,096,560. Similar techniques may be used in the manufacture of surgical aids wherein nonabsorbable fibers are combined with absorbable fibers composed of the polymers of this invention. The surgical utility of "bi-component filaments" containing absorbable and nonabsorbable components is described in U.S. Pat. No. 3,463,158 the teaching of which is incorporated herein by reference. Monofilaments of the polymers of the present invention may be woven or knitted to form an absorbable fabric having the structure illustrated in FIG. 5, useful surgically in hernia repair and in supporting damaged liver, kidney and other internal organs.

The polymers of the present invention are also useful in the manufacture of cast films and other solid surgical aids such as scleral buckling prostheses. Thus, cylindrical pins, screws as illustrated in FIG. 3, reinforcing plates, etc., may be machined from solid polymer having in vivo absorption characteristics depending upon the polymer composition and molecular weight.

Many different embodiments of this invention will be apparent to those skilled in the art and may be made without departing from the spirit and scope thereof. It is accordingly understood that this invention is not limited to the specific embodiments thereof except as defined in the appended claims.

We claim:

1. A synthetic absorbable suture of oriented fiber comprising an isomorphous polyoxalate polymer consisting essentially of units of cyclic and linear oxalates and having the general formula



wherein each R is



and from about 5 to 95 mol percent of the R units are I; A is trans 1,4-cyclohexylene or p-phenylene, n is 1 or 2 and is the same for I and II, and x is the degree of polymerization resulting in a fiber forming polymer having a molecular weight greater than about 10,000.

2. A suture of claim 1 wherein said fiber is a monofilament.

3. A suture of claim 1 wherein said fiber is a multifilament.

4. A suture of claim 3 wherein said multifilament fiber is a braid.

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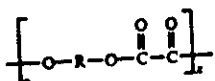
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5. A suture of claim 1 wherein n is 1 and A is trans 1,4-cyclohexylene.
 6. A suture of claim 1 wherein n is 2 and A is trans 1,4-cyclohexylene.
 7. A suture of claim 5 wherein from about 40 to 75 mol percent of the R units are of formula I.
 8. A suture of claim 1 wherein n is 1 and A is p-phenylene.
 9. A suture of claim 1 wherein n is 2 and A is p-phenylene.

10. A suture of claim 1 having a surgical needle attached to at least one end thereof.

11. A suture of claim 10 packaged in a sterile and dry environment within a hermetically sealed and substantially moisture impervious container.

12. The method of closing a wound in living tissue which comprises approximating the wound tissue with an absorbable suture comprising of sterile, oriented fiber comprising an isomorphous copolyoxalate polymer consisting essentially of units of cyclic and linear oxalates and having the general formula



wherein each R is



or



with from about 5 to 95 mol percent of the R units being I; A is trans 1,4-cyclohexylene or p-phenylene, n is 1 or 2 and is the same for I and II, and x is the degree of polymerization resulting in a fiber forming polymer having a molecular weight greater than about 10,000.

13. The method of claim 12 wherein said fiber is a monofilament.

14. The method of claim 12 wherein said fiber is a multifilament.

15. The method of claim 14 wherein said multifilament fiber is a braid.

16. The method of claim 12 wherein n is 1 and A is trans 1,4-cyclohexylene.

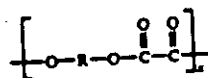
17. The method of claim 12 wherein n is 2 and A is trans 1,4-cyclohexylene.

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18. The method of claim 16 wherein units of formula I comprise from 40 to 75 mol percent of the R groups.

19. The method of claim 12 wherein A is p-phenylene.

20. A surgical prosthesis of a fabric manufactured at least in part from synthetic absorbable fibers comprising an isomorphous polyoxalate polymer consisting essentially of units of cyclic and linear oxalates and having the general formula:



wherein each R is

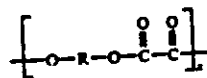


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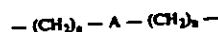


with from about 5 to 95 mol percent of the R units being I; A is trans 1,4-cyclohexylene or p-phenylene, n is 1 or 2 and is the same for I and II, and x is the degree of polymerization resulting in a fiber forming polymer having a molecular weight greater than about 10,000.

21. A surgical prosthesis of a solid surgical aid cast or machined from an absorbable polymer comprising an isomorphous polyoxalate polymer consisting essentially of units of cyclic and linear oxalates and having the general formula



wherein each R is



or



with from about 5 to 95 mol percent of the R units being I; A is trans 1,4-cyclohexylene or p-phenylene, n is 1 or 2, and is the same for I and II, and x is the degree of polymerization resulting in a fiber forming polymer having a molecular weight greater than about 10,000.

United States Patent [19]

Brennan et al.

[11] Patent Number: 4,959,069

[45] Date of Patent: Sep. 25, 1990

[54] **BRAIDED SURGICAL SUTURES**

[75] Inventors: Karl W. Brennan, Somerset; Allison M. Skinner, Long Valley, both of N.J.; Gregory Weaver, New Hope, Pa.

[73] Assignee: Ethicon, Inc., Somerville, N.J.

[21] Appl. No.: 424,622

[22] Filed: Oct. 20, 1989

[51] Int. Cl.³ A61B 17/00

[52] U.S. Cl. 606/228; 428/224; 87/7

[58] Field of Search 606/228, 229, 230, 231, 606/151; 138/123, 129; 139/317; 428/224

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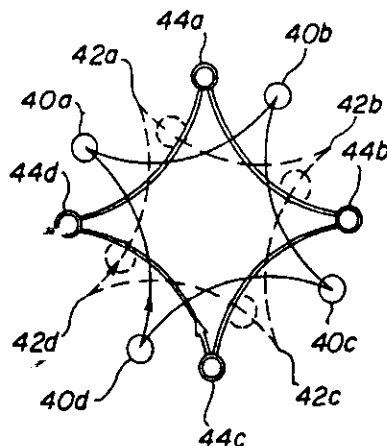
Primary Examiner—Randall L. Green

Assistant Examiner—Gary Jackson

[57] **ABSTRACT**

A braided surgical suture is provided which in a first embodiment is woven in a spiral braid. The suture is braided by moving thread carriers from position to position around a circular path. As each carrier moves it moves from its present position to a succeeding position which is at least two positions removed from its present position. Such spiral braided sutures are advantageously produced without core filaments, providing benefits in strength, smoothness, pliability and cylindrical uniformity without the discontinuity of properties characteristic of conventionally braided cored sutures. In a second embodiment the suture is woven in a lattice braid, providing a plurality of distributed core passageways for individual core fibers.

17 Claims, 4 Drawing Sheets



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FIG-1a

PRIOR ART

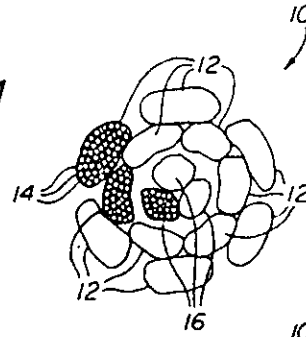


FIG-1b

PRIOR ART

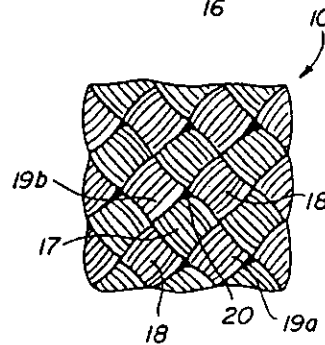
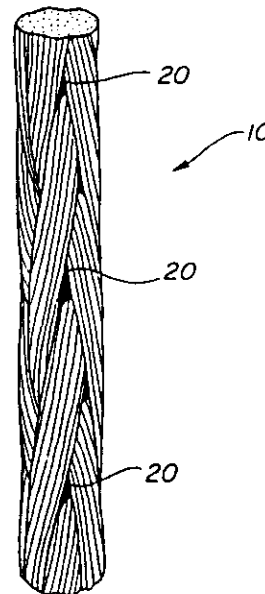


FIG-3

PRIOR ART



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FIG-2 PRIOR ART

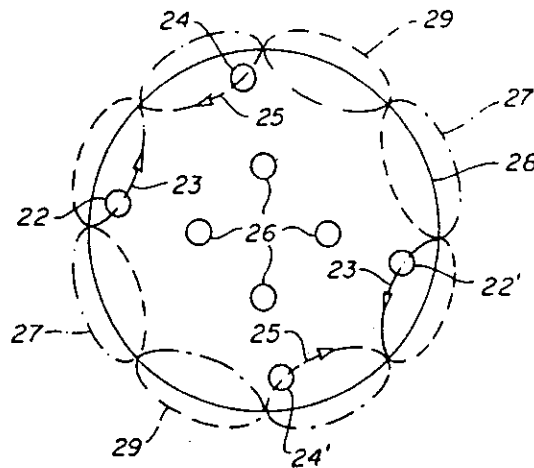


FIG-4a

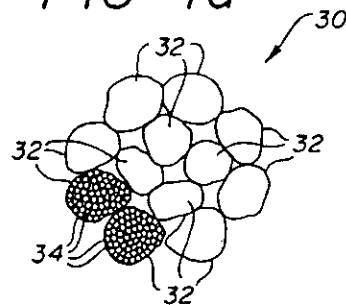
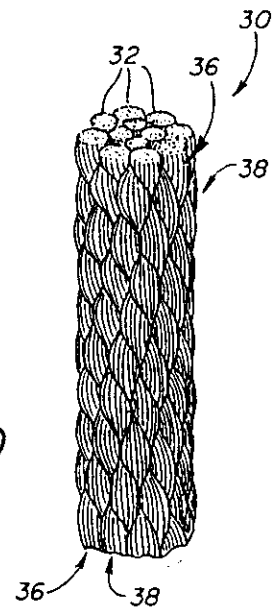


FIG-4b



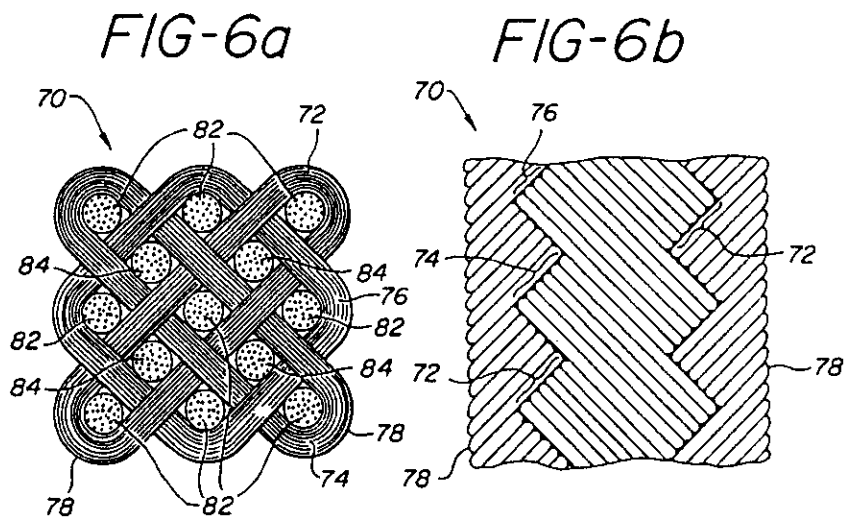
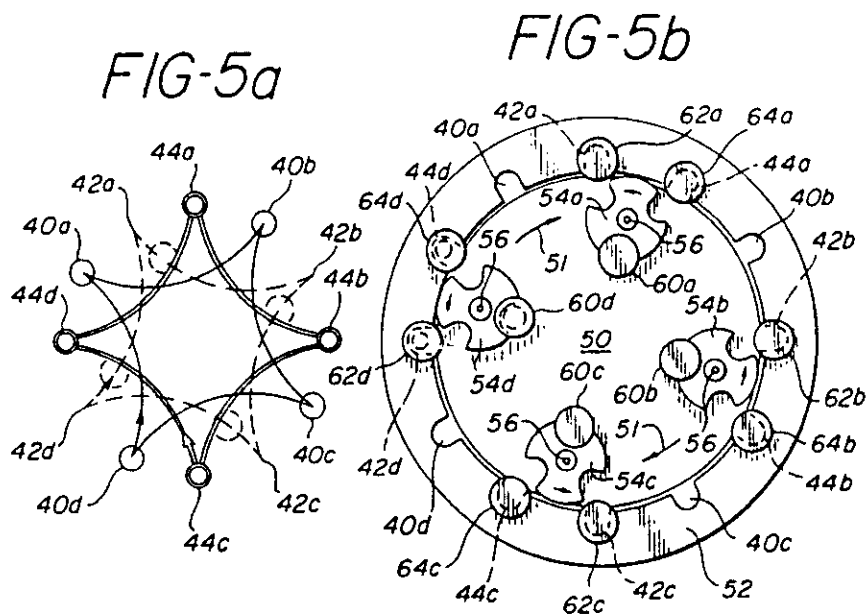
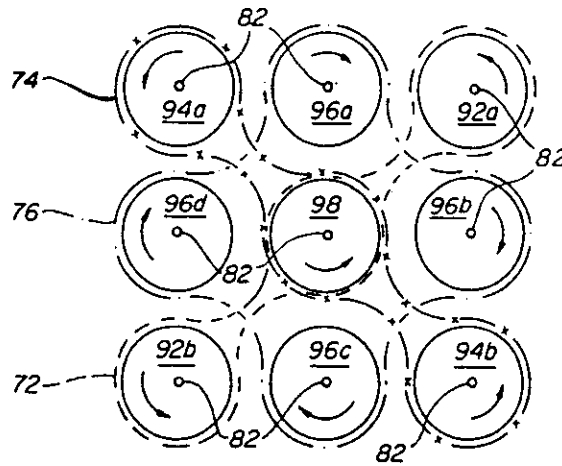


FIG-7



BRAIDED SURGICAL SUTURES

This invention relates to surgical sutures and, in particular, to braided surgical sutures which obviate the need for a central fiber core.

Surgical sutures may be manufactured in two general forms: monofilaments and multifilaments. Monofilament sutures are generally made of natural materials such as gut, or of extruded polymeric materials such as Nylon, polypropylene, or poly (p-dioxanone), and are highly regarded for their uniform, smooth construction and uniformly distributed tensile strength. However, monofilament sutures generally have the drawback of being fairly rigid and lacking pliability. Multifilament sutures consisting of a plurality of braided filaments of a fine gauge have been found to provide the characteristic of pliability which is often desired by surgeons. Such braided sutures may be made of poly(lactide-co-glycolide), polyglycolide, polyester, or silk, for example. But since braided sutures often lack substantial tensile strength, the braided filaments are conventionally braided in a tubular sheath around a core of longitudinally extending threads. Such braided sheath sutures with central cores are shown in U.S. Pat. No. 3,187,752; 4,043,344; and 4,047,533, for example.

Braided sutures with central core threads have been found to exhibit certain disadvantages, however. One is that the tensile strength of the suture is not evenly distributed between the braided sheath and the central core threads. As a consequence, when these sutures are stretched, the sheath and the core will respond differently to the application of the tensile forces. The sheath will respond to the forces independently of the central core threads, causing the central threads to move longitudinally relative to the surrounding sheath. The core threads can also flatten and redistribute themselves within the sheath instead of maintaining the desired rounded cross-sectional shape of the suture. It would be desirable for such tensile forces to be more uniformly distributed throughout the suture, so that all of the fibers of the suture will respond in unison to the tensile forces without distortion of the normal shape of the suture.

Conventionally braided sutures can also feel rough to the touch, due to the changing crossing pattern of the braided filaments, and the interstices formed where the braided fibers overlap and cross each other. To minimize this tactile characteristic it is often necessary to further process the braided suture by heating and stretching the suture. Furthermore, such interstices can trap and retain moisture in a wicking fashion. Retained moisture has been found to be a source of undesired deterioration of sutures made of certain materials, such as absorbable sutures made of poly(lactide-co-glycolide) or polyglycolide, and can also lead to retention of sources of infection within the braid. It would be desirable to form braided sutures which are smoother to the touch, and which do not exhibit interstices or passageways which can trap and retain moisture prior to use of the sutures.

It would further be desirable for braided sutures to match or exceed the breaking strength characteristics of presently available braided sutures with central core threads.

In accordance with the principles of the present invention, a braided suture is provided in which the filaments or threads are braided in a spiral pattern. Sutures

braided in a spiral pattern have been found to be capable of maintaining a uniformly rounded cross-sectional shape, and to distribute tensile forces uniformly throughout the braided fibers. Spiral braided sutures also do not form the tube-like structure of the conventional braiding pattern, which eliminates the need for a central fiber core. Since spiral braiding results in an outer sheath pattern in which the braided threads are all flowing in the same direction, the suture is much smoother to the touch than the conventionally braided suture. The smoothly flowing braided configuration also does not provide interstices which can trap undesired moisture in the suture. Furthermore, the spiral braided suture has been found to be stronger, smoother to the touch, and much more pliable than the conventionally braided suture.

In accordance with a further aspect of the present invention a suture is provided which is formed by lattice braiding. The lattice braided suture exhibits a plurality of interwoven threads in a generally rectangular cross-sectional configuration. The lattice braid may be woven around a plurality of core threads distributed in the internal interstices of the lattice network and interlocked into position, unlike the central bundle of core threads of the conventionally braided suture. The lattice braided suture has been found to be superior to the conventionally braided core suture in that it does not exhibit "core pop", the tendency of the core filaments to break through the braided sheath as the suture is bent.

In the drawings:

FIGS. 1a and 1b illustrate diagrammatic cross-sectional and side views of a conventionally braided suture;

FIG. 2 illustrates the braiding pattern of a conventionally braided suture;

FIG. 3 is a drawing of an enlarged view of the outer sheath of a conventionally braided suture;

FIGS. 4a and 4b illustrate diagrammatic cross-sectional and side views of a spiral braided suture of the present invention;

FIG. 5a illustrates the braiding pattern of a spiral braided suture of the present invention;

FIG. 5b is a diagrammatic plan view of a mechanism used to braid a spiral braided suture of the present invention;

FIGS. 6a and 6b illustrate the braiding pattern and outside sheath of a lattice braided suture of the present invention; and

FIG. 7 is a diagrammatic plan view of a mechanism used to braid a lattice braided suture of the present invention.

Referring first to FIGURE 1a, a conventionally braided suture 10 is shown in diagrammatic cross-section. The suture 10 comprises a plurality of threads or carriers 12 which are interwoven to form the braided sheath. Each thread generally comprises a number of individual fibers 14. The braided threads 12 form a tubular sheath around the central core threads 16, which extend longitudinally through the tubular sheath. The sheath is braided using at least three threads, or a greater even number of threads, such as 4, 6, 8, etc. The core may comprise one or any greater number of threads. The suture 10 is shown in FIG. 1a to exhibit its desired cylindrical uniformity. However, it has been found that during handling, heating and stretching of the suture during manufacture the tubular sheath can distort to an oval or oblong shape, with the core threads

16 redistributed in the sheath in an irregular or linear configuration.

As a consequence of the structural independence of the braided sheath and the core threads, the sheath and core will unevenly distribute tensile forces among these two substructures when the suture is stretched, causing the two to move relative to each other. The relative movement of the two can result in the formation of spaces or pockets inside the sheath, between threads 16 of the core and the surrounding sheath. These spaces can entrap moisture through the mechanism of wicking, resulting in premature deterioration and weakening of the suture in vivo use of the suture.

The conventionally braided suture is woven as indicated by the braiding pattern of FIG. 2, shown in a plan view. The individual threads of the braided sheath feed from spools mounted on carriers 22, 22' and 24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction. In the illustrated embodiment carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. Disposed within the center of the loop 28 are carriers 26 which dispense the core threads of the suture. Thus, the moving carriers 22, 22', 24, and 24' dispense threads which intertwine to form the braided sheath, and the sheath is formed around the centrally located core threads dispensed from carriers 26. The threads from all of the carriers in a constructed embodiment of FIG. 2 are dispensed upward with respect to the plane of the drawing, and the braided suture is taken up on a reel located above the plane of the drawing.

FIG. 1b is an illustration of the outside of the braided sheath of the suture 10 of FIG. 1a, showing the crossing pattern of the braided threads 12. Each thread is composed of a number of individual fibers as indicated by the lines on each thread. Where each thread appears on the outside of the sheath it is seen to be orthogonally directed with respect to the thread it crosses over, the thread from beneath which it appears, and the thread it next crosses under. For instance, thread 17 is orthogonally directed with respect to thread 18 on either side of thread 17 where thread 17 crosses over thread 18. The thread 17 is also orthogonally directed with respect to thread 19a from beneath which it appears, and with respect to thread 19b which it next crosses under.

This orthogonal crossing relationship of the braided threads results in the formation of small interstices or voids 20 where the threads cross one another, as shown in FIG. 3, which shows a drawing reproduction of an enlarged photograph of a conventionally braided suture. These voids 20 can entrap moisture which can lead to premature deterioration of the suture, and can also entrap bacteria and other sources of infection causing complication of wound healing.

Referring now to FIG. 4a, a spiral braided suture 30 of the present invention is shown in diagrammatic cross-section. The braided suture 30 comprises a plurality of interwoven and interlocked threads 32, each of which may comprise a number of individual fibers 34. Due to the interlocking of the threads 32, no central passage-way is formed in which moisture can become en-

trapped. The interlocking of the threads also causes the threads to move in unison as a continuous structure, thereby uniformly distributing tensile forces when the suture 30 is pulled or stretched.

The spiral pattern of the suture 30 is clearly shown in the outside view of the suture of FIG. 4b. The threads on the outside are seen to be aligned in a spiral pattern which ascends from the lower left to the upper right in the drawing as the outer threads precess around the outer surface of the suture. One spiraling set of threads is indicated between arrows 36, and another set is indicated between arrows 38. As the pattern spirals, individual threads on the outer surface are in a parallel orientation with respect to each other and with respect to the longitudinal length of the suture as they continually reappear in the spiral pattern.

With all threads aligned in the parallel, offset spiral pattern of FIG. 4b, it may be seen that there are no voids or interstices formed on the outside surface of the suture. This is due to the parallel orientation of the threads, as opposed to the orthogonally directed crossing pattern of the threads of the conventionally braided suture of FIGS. 1b and 3. The parallel orientation of the outer appearing threads also provides a smoother feel to the suture, since the hand will sense the continuous, longitudinal orientation of the parallel threads as it is run along the suture.

A spiral braided suture of the present invention is formed of four or more interwoven threads. Preferably at least nine threads are braided in groups of three, and a braiding pattern for a spiral braided suture of twelve threads, arranged in groups of four, is shown in FIG. 5a. In the illustrated pattern the carriers move sequentially in the same direction around the circular loop of carriers. As they move, each carrier moves from its present position to a succeeding position which is at least two positions removed from its present position. In the illustration of FIG. 5a, each carrier moves to the third succeeding position around the loop. The twelve carriers are grouped into three groups of four carriers each. In the first group, carriers move in unison between positions 42a, 42b, 42c, and 42d. The carrier at position 42a moves to position 42b, passing by positions 44a and 40b as it does so. As it moves, the carrier at position 42b is moving to position 42c, bypassing positions 44b and 40c. At the same time the carrier at position 42c is moving to position 42d, and the carrier at position 42d is moving to position 40a.

After these four carriers have moved to their new positions in unison, the carriers at positions 44a, 44b, 44c, and 44d move to their succeeding positions. Then the carriers at positions 40b, 40c, 40d, and 40a move to their succeeding positions. The sequence then repeats in the same fashion.

Apparatus for executing the spiral braiding pattern of FIG. 5a is diagrammatically shown in FIG. 5b. The apparatus comprises a rotating central platform 50 which is surrounded by an annular plate 52. The platform 50 rotates as indicated by arrows 51. Pivotaly mounted on the platform 50 are four rotating carrier pickups 54a, 54b, 54c, and 54d which rotate about pivot points 56. Each pickup has a number of apertures which engage the carriers to move them to their succeeding positions, the number being chosen in correspondence with the number of positions to be bypassed as the carriers move in their braiding pattern. In the illustrated embodiment the number of apertures is three, enabling the carriers to bypass two positions each time they are

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moved. The twelve carrier positions are delineated by rounded openings in the annular plate 52, four of which are indicated at 40a, 40b, 40c, and 40d. The carriers which carry spools of thread are indicated at 60, 62, and 64.

In operation pickup 54a will engage the carrier 60a at position 40a. As the central platform 50 rotates the pickup 54a simultaneously rotates to transfer the carrier 60a from position 40a to position 40b, which has just been vacated by carrier 60b. The carrier 60a is seen to bypass carriers 62a and 64a as it travels to its succeeding position 40b. As carrier 60a is transferred by pickup 54a, pickups 54b, 54c, and 54d simultaneously are transferring carriers 60b, 60c, and 60d to their succeeding positions.

As the pickup 54a is about to deposit the carrier 60a at position 40b, the pickup engages carrier 64a to begin transferring that carrier to its succeeding position. The carriers 64b, 64c, and 64d are similarly engaged simultaneously by the other three pickups. After the carriers 60a, 60b, 60c, and 60d have been deposited at their new positions and the carriers 64a, 64b, 64c, and 64d are enroute to their succeeding positions, the pickups engage the carriers 62a, 62b, 62c, and 62d for transfer. As this sequence of carrier transfer continues, threads from the spools on the carriers are dispensed upward with respect to the plane of the drawing and the braided suture is taken up on a reel located above the apparatus.

A lattice braided suture 70 of the present invention is shown in FIG. 6a, which schematically illustrates the structure of the lattice braid. In FIG. 6a, three or more threads are braided in a lattice pattern. One thread or group of threads traverses the path 72, a loop extending from the upper right to the lower left of the drawing. As the carrier or carriers dispensing thread on path 72 move around this path, they alternately cross over and under the paths of the other threads that they encounter, the crossing pattern being determined by the times and locations of travel of the respective carriers. In a similar fashion a second carrier or carriers dispensing thread traverse a path 74 from the lower right to the upper left of the pattern. Like the first path, the thread dispensed from carriers travelling this path alternately crosses over and under the other paths it encounters. A third path 76 travels around the intersection of the first path 72 and the second path 74. Like the first two paths, the thread dispensed from the carrier or carriers traversing path 76 alternately crosses over and under the threads of the other paths it encounters.

The lattice braid of FIG. 6a is seen to exhibit a generally square shape in cross-section with rounded corners. While the lattice braided suture has been found to provide less tensile strength than the spiral braided suture, the lattice braided suture can be strengthened by the inclusion of individual core threads running longitudinally through the interlocking lattice. A number of core threads may be located at the positions indicated at 82 in the lattice, at the positions indicated at 84, or both. This uniform distribution of core threads throughout the lattice, which results in secure capture of the individual threads within the loops of the lattice, has been found to provide a uniform distribution of tensile forces throughout the suture.

The outside of the lattice braided suture 70 is illustratively shown in FIG. 6b. The outer threads of the lattice are seen to be distributed in an angularly offset, generally parallel configuration. The drawing shows the generally parallel alignment of threads 72, 74, and 76 on the

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outside of the suture, forming a substantially smooth, longitudinally extending outer thread surface on each side of the square configuration. The rounded corners 78, shown on each side of the drawing, are also seen to smoothly extend along the length of the suture.

Apparatus for braiding the lattice braided suture of FIG. 6a is schematically shown in FIG. 7. The apparatus includes a plurality of rotating discs which transfer the carriers around and along their intended paths of travel. In a preferred embodiment there are three carriers traversing each path. Extending through the center of each rotating disc is a core thread 82, each of which becomes engaged in the lattice loops formed around its respective disc. The path 72 is traversed by carriers which rotate around disc 92a and are then transferred to the central disc 98. Each carrier travels halfway around disc 98 and is then transferred to disc 92b. The carriers travel around disc 92b and back to the central disc 98. After travelling around the other side of disc 98 each carrier is transferred back to rotating disc 92a and its starting point.

In a similar manner a second group of carriers on the path 74 travel around disc 94a and are transferred to the central disc 98. After travelling halfway around disc 98 each carrier is transferred to disc 94b. Each carrier travels around the rotating disc 94b, back to the other side of the central disc 98, and is returned to disc 94a and its starting point.

The third path 76 passes around rotating discs 96a, 96b, 96c, and 96d. The carriers which travel this path 76 pass around three-quarters of each disc before being transferred to the succeeding disc in the loop. As each carrier traverses the path 76 it is seen to pass inside the end discs of the other two paths 72 and 74, thereby enclosing the intersection of these two paths at the central disc 98.

The apparatus of FIG. 7 may be operated with a plurality of carriers travelling each path simultaneously. For instance, the apparatus may be operated with three carriers on each path to form a lattice braid of 9 threads. Alternatively each path may include 4 carriers for a total of 12 braided threads. As a third example, the apparatus may operate with 6 carriers on each path for a total of 18 threads in the braided suture.

Spiral braided sutures of the present invention can be expected to provide a 20% improvement in smoothness over conventionally braided sutures, a 20% improvement in pliability, and a 50% improvement in cylindrical uniformity. The improvement in smoothness is due to the parallel alignment of the suture threads on the outside of the spiral braided suture. The improvement in pliability is due to the thread crossovers of the spiral braid, which enhances fiber mobility; the individual threads in the spiral braided suture will easily move relative to each other as the suture is bent. And since there is no core to become misaligned or misshapen, cylindrical uniformity is improved.

Improvements in breaking strength can also be expected for the spiral braided suture. In a test of breaking strength remaining (BSR) after 21 days of in vivo use of an absorbable suture of conventional braid, typically 40-50% of the breaking strength remains. A 15-20% improvement in BSR can be expected in use of a spiral braided suture of the present invention under the same conditions.

The lattice braided suture provides the capability of producing a high quality composite suture, in which advantage is taken of the different characteristics of one

type of material for the braid and another type of material for the core threads. As discussed above, the lattice braided suture is substantially more immune to the problem of core pop than the conventionally braided suture, since the core threads are distributed throughout the structure of the braid and are not positioned in a single central location. Both the spiral and lattice braided sutures have been found to exhibit less surface area exposed to ambient conditions, and hence less exposure to moisture, than conventionally braided sutures.

What is claimed is:

1. A braided surgical suture in which a plurality of surgically compatible filaments are woven in a spiral braid by moving filament dispensers to different positions around a closed loop, wherein an individual dispenser in the loop is moved from its current position to a succeeding position which is at least two positions removed from said current position.

2. The braided surgical suture of claim 1, wherein the number of filaments is at least nine.

3. The braided surgical suture of claim 2, wherein said filament dispensers move around said loop in the same direction.

4. The braided surgical suture of claim 3, wherein said filament dispensers are organized in three uniformly distributed groups around said loop and the dispensers in each group move around said loop in unison.

5. The braided surgical suture of claim 3, wherein the number of filaments is twelve and wherein an individual dispenser in the loop is moved from its current position to a succeeding position which is three positions removed from said current position.

6. The braided surgical suture of claim 1, wherein the portions of said filaments which are visible on the outside of said braided suture are oriented substantially parallel to each other and are distributed in patterns which spiral around the outside of said suture.

7. The braided surgical suture of claim 1, wherein said surgically compatible filaments are woven in a

spiral braid without any central, longitudinally extending core filaments.

8. A braided surgical suture in which a plurality of surgically compatible filaments are woven in a lattice braid by moving filament dispensers in three closed loop paths, a first and second of said paths being generally oblong and crossing over each other at a central intersection, and the third of said paths passing through the ends of said first and second paths outside said central intersection.

9. The braided surgical suture of claim 8, wherein said suture in cross-section exhibits a generally rectangular shape, with filaments traversing said ends of said first and second paths being located at the corners of said rectangular shape.

10. The braided surgical suture of claim 8, wherein each moving filament dispenser alternately passes over then under the filaments dispensed on the paths it intersects.

11. The braided surgical suture of claim 10, wherein there are at least three filament dispensers traversing each of said paths.

12. The braided surgical suture of claim 8, wherein there are formed a plurality of core filament passageways located adjacent to the points of intersection of two or more of said paths.

13. The braided surgical suture of claim 12, further comprising at least four core filaments located in ones of said passageways.

14. The braided surgical suture of claim 13, wherein said core filaments are symmetrically distributed with respect to said point of intersection.

15. The braided surgical suture of claim 13, wherein said core filaments are made of a different surgically compatible material than that of said woven filaments.

16. The braided surgical suture of claim 12, further comprising at least nine core filaments located in ones of said passageways.

17. The braided surgical suture of claim 12, further comprising at least thirteen core filaments located in ones of said passageways.

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United States Patent [19]

Silvestrini

[11] Patent Number: 4,979,956

[45] Date of Patent: Dec. 25, 1990

[54] **DEVICE AND METHOD FOR TENDON AND LIGAMENT REPAIR**[75] Inventor: **Thomas A. Silvestrini**, East Lyme, Conn.[73] Assignee: **Pfizer Hospital Products Group, Inc.**, New York, N.Y.[21] Appl. No.: **378,437**[22] Filed: **Jul. 10, 1989****Related U.S. Application Data**

[63] Continuation of Ser. No. 115,087, Oct. 30, 1987, abandoned.

[51] Int. Cl.³ A61F 2/06

[52] U.S. Cl. 623/13

[58] Field of Search 623/11, 12, 16, 13, 623/18

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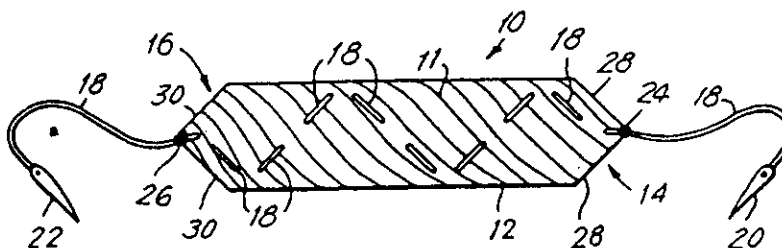
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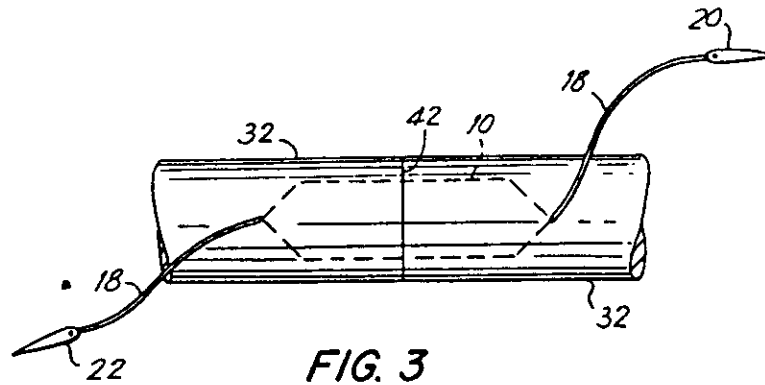
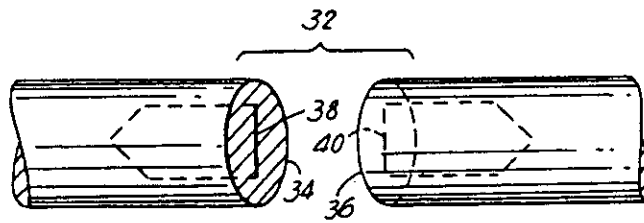
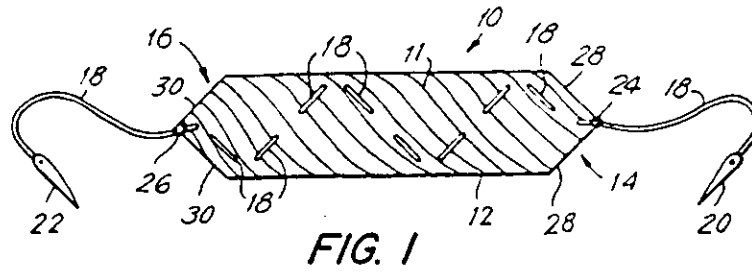
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Primary Examiner—David J. Isabella
 Attorney, Agent, or Firm—Peter C. Richardson;
 Lawrence C. Akers; John L. LaPierre

ABSTRACT

[57] A device, suitable for use in repairing a lacerated or severed tendon, particularly a hand flexor tendon, having a flat band body with opposite ends of the body designed to anchor connecting sutures. The device also finds applicability in the repair of lacerated or severed ligaments. Also disclosed is a method of repairing a severed tendon by implanting a flat band device suturing together the device and the tendon to effect an anastomosis along approximated ends of the severed tendon. Further disclosed is a method of repairing a lacerated or severed ligament.

28 Claims, 2 Drawing Sheets



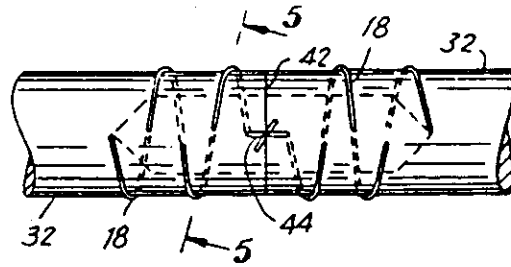


FIG. 4

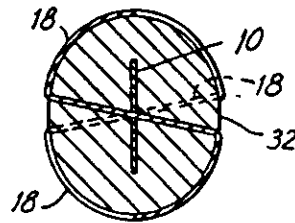


FIG. 5

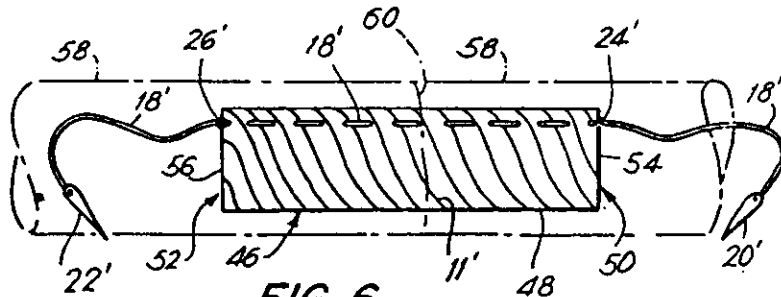


FIG. 6

DEVICE AND METHOD FOR TENDON AND LIGAMENT REPAIR

This is a continuation, of application Ser. No. 5 115,087, filed on Oct. 30, 1987, now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates to a device for repairing severed or lacerated tendons and ligaments and, more particularly, the invention relates to a device having a flat band body constructed of resilient synthetic textile fiber and capable of receiving a suture element secured thereto at opposite ends of the body. Also contemplated by the invention are methods of anastomosing ends of severed or lacerated tendons and ligaments along an interface of approximated ends, by placing a device intratendonously, in the case of a tendon, or in juxtaposition, in the case of a ligament, bridging or spanning approximated ends, and suturing together either the tendon and the device or the ligament and the device. The objective is to provide a device and method for restoring tendons and ligaments, as nearly as possible, to their pre-damaged condition.

The successful repair of tendons, particularly hand flexor tendons, has been a problem for surgeons for many years. The past and current approach most commonly used by surgeons to achieve tendon repair is to anastomose severed tendons by using one of a variety of suturing techniques. A number of such techniques are commonly known and referred to as Bunnell, Kessler, Kliener, Tsuge and Becker, to name but a few. These techniques, while useful, are not entirely satisfactory because they allow surgeons to achieve successful repairs in only about 70% of the patients treated. Therefore, in view of the history of suture techniques which have been proposed and implemented from time to time by surgeons without any real improvement in repair strength or surgical result, the need for an improved device and method of anastomosis were clearly evident.

In addition to the foregoing suturing techniques most often used in tendon repair, in an effort to overcome the deficiencies encountered in the straight suturing approach, other devices and approaches have recently been tried to effect tendon repair. A typical device encountered might be one like that disclosed in U.S. Pat. No. 4,469,101. The teaching embodied in this patent specifies a structure having an open network or mesh of helically formed members to define a hollow tubular device wherein opposing ends of a lacerated tendon are introduced and brought into contact within the tube. The opposite ends of the tube are then sutured to the outer tendon wall and the contacting tendon ends are allowed to heal. Another device typically encountered in tendon repair might be one like that disclosed in U.S. Pat. No. 4,501,029. This patent provides a continuous solid wall tubular device having in communication therewith a number of transversely extending passages. The tube is inserted between a replacement tendon and the tendon sheath. After blood supply from the sheath to the replacement tendon is established through the tubular passages, free movement of the tendon is established within the sheath. A third device encountered might be the plastic prosthetic tendon disclosed in U.S. Pat. No. 3,176,316. This patent provides a prosthesis having a solid central segment and hollow tubular ends comprising a mesh network wherein ends of a tendon

are introduced and the prosthesis is sutured to the tendon.

There are certain disadvantages associated with each of the aforementioned tendon repair techniques and devices which the present inventive device and method either overcome or substantially lessen. Specifically, through the use of suturing techniques alone, irritations are minimized since sutures are buried inside the endotendon, but the strength of the anastomosis is not strong enough to allow aggressive mobility during healing. Consequently, there often occurs dehiscence of the suture leading to separation of approximated tendon ends, tissue ingrowth and slow or incomplete tendon healing. Inherent in the tubular mesh devices which are sutured to the tendon at ends of the devices is the exposure of a large amount of synthetic material on the outside of the epitenon which can cause excessive irritations. These irritations frequently lead to adhesions between the injured tendon and the tendon surrounding which leads to retarded healing. The inventive device offers a minimum of irritation since it is substantially buried inside the endotendon, yet it offers higher strength of the anastomosed tendon compared to repairs using sutures. Lastly, the present device is one of structural simplicity which avoids both the complex geometry presented in the solid wall tubular device having a series of selectively positioned blood conveying passageways and the need to precisely locate such a prosthesis in the body to assure an adequate blood supply to the replacement tendon.

It should be understood that, while much of the foregoing discussion is directed toward tendon repair, the teachings encountered are also generally applicable to the repair of damaged ligaments. Clearly, there exists a need for a repair device which fosters superior mechanical repair properties and better healing characteristics than is currently found in the relevant surgical field. The present inventive device and method satisfies the need and, hence, advances the art field of tendon and ligament repair.

SUMMARY OF THE INVENTION

The present invention relates to a device used for repairing severed connective tissue of tendons and ligaments by approximating ends of the severed tissue and comprises an elongated body portion having a flat band structure with the body portion at opposite ends adapted to be connected to at least one needle bearing suture. The body structure may be a non-woven fabric, a composite reinforced with chopped fiber, a polymer sheet or a fabric which can be selected from a class of warp knits, weaves, nets and braids. The preferred braided fabric would be a triaxial braid or a flat band triaxial tube having either a monocomponent or bicomponent fiber element selected from a polymeric grouping and may include an elastomeric component. The preferred polymer for a monocomponent device body would be polyethylene terephthalate while for a bicomponent device the preferred polymers for the device body would be polyethylene terephthalate and polyester/polyether block copolymer. A suture or sutures may be lock stitched to opposite ends of the device body and may be incorporated into the body structure axially in either a longitudinal direction or in a bias direction. Additionally, a suture or sutures may be sewn into the body. The device body and associated suture or sutures may be covered with one or more gel coatings selected from a class of hydrogels with a preferred

coating being crosslinked calcium alginate. The body portion may assume a number of shapes but either a rectangle or a polygon, having ends tapered substantially to a point, is preferred. The ends of the body portion are preferably sealed to maintain edge integrity.

Also contemplated within the scope of the present invention are methods for repairing severed connective tissue of tendons and ligaments utilizing the inventive device heretofore described. Specifically, one method comprises the steps of creating a slot in the tissue of each opposing end of a severed tendon, where severance occurred, inserting a first end of the device into one of the incised slots, inserting a second end of the device into the other of the incised slots, approximating opposing ends of the severed tissue, enclosing the device and therewithin bridging the ends, and suturing the tendon and the device together, passing sutures through the tendon and the implanted device along at least a portion of the length of the device, to anastomose the tendon along approximated ends of the severed connective tissue. A second method, relating to the repair of severed connective tissue of a ligament, comprises the steps of providing at least one inventive device, approximating opposing ends of the severed tissue, juxtaposing the ligament and the device with the device spanning approximated ends, and suturing the ligament and the device together, passing sutures through the ligament and the juxtaposed device along at least a portion of the length of the device, to anastomose the ligament along approximated ends of the severed connective tissue. In each of the methods, suturing will span at least the approximated ends and, preferably, suturing will be performed along substantially the entire length of the device.

The various features of novelty which characterize the invention are pointed out with particularity in the claims annexed to and forming a part of this disclosure. For a better understanding of the invention, its operating advantages and specific results obtained by its use, reference should be made to the corresponding drawings and descriptive matter in which there is illustrated and described typical embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an enlarged schematic representation of a tendon and ligament repair device, in accordance with the principles of the present invention, illustrating a flat band triaxial braid fabric structure having a single bias suture incorporated into the fabric body with the suture lock stitched to the body at opposite ends of the body.

FIG. 2 schematically illustrates a severed tendon, drawn at reduced scale, with slots incised in the tendon ends, before implantation of the repair device.

FIG. 3 is similar to FIG. 2, but with tendon ends approximated, and schematically illustrates the tendon repair device of FIG. 1 located within the endotendon prior to suturing.

FIG. 4 is similar to FIG. 3 and illustrates a completed repair showing suture penetration of both tendon and fabric body uniting tendon and device.

FIG. 5 is a cross-sectional view taken along line 5—5 of FIG. 4.

FIG. 6 is an enlarged schematic alternate embodiment of the invention showing in phantom a ligament with approximated ends and a flat band triaxial braid fabric structure, in place but prior to suturing, with a single axial suture incorporated into the fabric body

with the suture lock stitched to the body at opposite ends thereof.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The description herein presented refers to the accompanying drawings in which like reference numerals refer to like parts throughout the several views, and in which, referring to FIG. 1, there is illustrated a repair device 10 of the present invention. The device has an elongated body portion 12 of flat band structural configuration, preferably a triaxial braid with the braid schematically designated as 11, and at a first end 14 and at a second end 16 a suture 18, having needles 20 and 22 at opposite ends, is connected or anchored to the body ends by a locking stitches 24 and 26. It should be understood that many types of knots or locking stitches, such as a double throw suture locking stitch, would be suitable to anchor the suture to the body portion. Locking the suture to the body could be accomplished at any time, as desired. The device shown in FIG. 1, it should be remembered, is a schematic representation and, therein depicted, the device has a flat band triaxial braid fabric structure with a single bias suture braided into the fabric body. It should also be understood that more than one suture could be attached to or incorporated into the fabric body and locked to the body ends. Furthermore, a suture or sutures could be sewn or stitched to the body along the body length instead of being braided into the body. In the preferred form of the device, the lock stitching of the suture to the ends of the braid body prevents the braid structure from bunching during insertion into tissue. The stitching also serves to center the suture pull of the device, thereby easing the insertion of the device into connective tissue. Also contemplated within the scope of the invention is a suture or sutures not incorporated into the fabric body per se but merely locked to one or both of the body ends. The ends 14 and 16 may be sealed along edges 28 and 30 to maintain edge integrity. Edge sealing may be accomplished using an ultrasonic sealing process or other means of heat treatment to keep edges from unraveling or separating.

The device body portion may be structurally configured as a non-woven fabric, a polymer reinforced with chopped fiber, a polymer sheet, a warp knit, a weave, a net or a braid. The construction of the desired flat band fabric into any one of these body portion structural configurations would be within the skill of those who manufacture textile products. A preferred structure would be a braid, preferably a triaxial braid. A flat band or flattened triaxial tube is within the scope of the invention. A triaxially-braided fabric, such as the ones schematically depicted in FIG. 1 and FIG. 6, and the methods of manufacturing them in different configurations, namely, flat bands, flat tubes, tubes, patches and strips, to name but a few, are well known to those skilled in the art of manufacturing braided polymeric articles. The triaxial braid may consist of a monocomponent fiber selected from a group of polymers consisting of polyethylene terephthalate, polyethylene, polypropylene, polyaramid, polyamide, polyetheretherketone, polyester/polyether block copolymer, liquid crystal polymeric fiber, nylon and carbon. The preferred polymer would be polyethylene terephthalate. The triaxial braid may also have a bicomponent fiber makeup with its components selected from the same polymer grouping. One of the components of the bicomponent

braided should be elastomeric with the preferred elastomer being polyester/polyether block copolymer. The preferred bicomponent braid comprises a first component of polyethylene terephthalate and a second component of polyester/polyether block copolymer.

The device may be coated to improve the ease of surgical installation and to minimize irritation to tissue during healing. The suture or sutures could also be coated to minimize adhesions formed during healing. The coating could be a gel, specifically a hydrogel, selected from the group consisting of sodium alginate, hyaluronic acid, crosslinked hyaluronic acid, cross-linked calcium alginate and a calcium alginate cross-linked hyaluronic acid mixture. The preferred lubricious coating for the device and sutures is crosslinked calcium alginate.

The device body as shown in FIG. 1 defines a polygon having opposed longitudinal ends each tapering to a point with the points, preferably, lying along the central longitudinal axis. The body may, however, as is shown in FIG. 6, take a rectangular shape. Other flat band structural shapes would be suitable and are within the scope of the present invention.

Turning to FIG. 2 through FIG. 5, in FIG. 2 there is shown severed connective tissue of a tendon 32 having separated ends 34 and 36. In each end 34 and 36, slots 38 and 40 have been incised within the endotendon using a suitable blade or cutting device (not shown). Each slot 38 and 40 will preferably be configured to conform substantially to one half the size of the repair device 10. FIG. 3 shows device 10 located within slots 38 and 40, suture 18 at opposite ends 14 and 16 of device 10 passing through tendon 32, and separated tissue ends 34 and 36 approximated as shown at 42. Device 10 is closed within the approximated tissue, bridging ends 34 and 36 which are in contact along joint 42. FIG. 4 and FIG. 5 depict a completed repair wherein the tendon and the device have been sutured together and the suture ends tied at 44. Suturing of the device into the tendon can be accomplished in many different ways. Thus, the device does not restrict the personal suturing preference of different surgeons. Anastomosis of the tendon will occur along approximated ends at 42. Suturing should span at least the approximated ends and, preferably, suturing should be performed along substantially the entire length of the implanted device 10.

Turning to FIG. 6, there is schematically shown an alternate embodiment of the invention. Here depicted is a rectangular flat band repair device 46 having a triaxially braided fabric structure 11' and a suture 18', bearing needles 20' and 22', incorporated into elongated body portion 48 and axially oriented in a longitudinal direction. At first and second ends 50 and 52, suture 18' is affixed to the body ends by locking stitches 24' and 26'. As aforementioned in respect to the device 10, many types of knots or locking stitches would be suitable to affix the suture to the body portion and stitching could be accomplished when desired, namely, at time of manufacture or by a surgeon prior to device use. Lock stitching would be particularly useful, in addition to ease in installation, that is, prevention of fabric bunching, to keep the suture from being pulled through the fabric. More than one suture could be used and attached to or incorporated into the body fabric. Additionally, a suture might be sewn to the body along the length of the body rather than being braided into the body. The ends 50 and 52 may be sealed along edges 54 and 56 to maintain edge integrity, as in the case of device 10. All of the

other structural features associated with device 10 are equally suitable for device 46.

In FIG. 6, device 46 is shown to be particularly useful in the repair of severed connective tissue of a ligament, illustrated in phantom and designated as 58. It should be understood, however, that a device of rectangular configuration would be equally useful in tendon repair and slots 38 and 40, as shown in FIG. 2, could assume a rectangular shape. Likewise, device 10 would be equally suitable in the repair of a ligament. Device 46, as provided in FIG. 6, is shown positioned alongside ligament 58 having severed ends approximated at 60. The device spans the approximated ends. It should be understood that more than one device could be used for the repair. While a completed repair is not shown in FIG. 6, a suturing technique like that shown in FIG. 4, and other techniques described in respect thereto, could be used to suture together ligament 58 and device 46. Anastomosis of the ligament will occur along approximated tissue ends at 60. Suturing should span at least the approximated ends and, preferably, suturing should be performed along substantially the entire length of device 46. In each of the repair techniques, namely, tendon and ligament, devices 10 and 46 are biocompatible and can be made from permanent, non-body absorbable materials, or from resorbable materials.

As heretofore mentioned, braiding can be accomplished using known technology and the inventive device can be manufactured using existing braiding machines modified to incorporate longitudinal fibers into the braided structures. By way of example, and not to be construed as limiting the invention, a 0.07 inch wide monocomponent polyethylene terephthalate device 10 can be braided on a 32-carrier triaxial braider using 70 denier white polyethylene terephthalate type 52 multifilament yarns and a single green 4-0 polyethylene terephthalate suture. The finished product is composed of 31 polyethylene terephthalate yarns and one 4-0 polyethylene terephthalate suture on the bias and 16 polyethylene terephthalate yarns on the longitudinal axis. In another example, a 0.07 inch wide bicomponent device 10 can be braided on a 24-carrier triaxial braider using 220 denier polyester/polyether block copolymer monofilaments, 70 denier white polyethylene terephthalate type 52 multifilament yarns, and a single green 4-0 polyethylene terephthalate suture. The finished construction is composed of 23 polyethylene terephthalate yarns and one 4-0 polyethylene terephthalate suture on the bias, and 12 polyester/polyether block copolymer fibers on the longitudinal axis. It should be understood that wider or narrower devices could be manufactured. The device is made from safe materials that surgeons are comfortable implanting and the device can easily be made in a variety of sizes to address different soft tissue repair situations. Device needles could be swaged onto the suture ends of affixed by other suitable means. Laboratory testing of a repair device used to anastomose explanted canine and bovine tendon has demonstrated that the initial strength of the repair junction is approximately twice the strength of tendon repairs made using conventional suturing techniques.

While in accordance with provisions of the statutes there is described herein specific embodiments of the invention, those skilled in the art will understand that changes may be made in the form of the invention covered by the claims appended hereto without departing from the scope and spirit thereof, and that certain features of the invention may sometimes be used to an

4,979,956

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advantage without corresponding use of the other features.

I claim:

1. A device for use in repairing severed connective tissue of tendons and ligaments by approximating severed ends of said tissue bringing said tissue ends into abutment comprising an elongated body having a flat band structure, said body being sized and configured for enclosure within said abutting tissue ends, and with said body at first and second opposed non-bifurcated ends adapted to be connected to at least one needle bearing suture, with said suture being incorporated into said body substantially the length thereof, said suture being oriented in a bias direction.

2. The device according to claim 1 wherein said structure is a non-woven fabric.

3. The device according to claim 1 wherein said structure is a polymer reinforced with chopped fiber.

4. The device according to claim 1 wherein said structure is a polymer sheet.

5. The device according to claim 1 wherein said structure is a fabric selected from the group consisting of warp knits, weaves, nets and braids.

6. The device according to claim 5 wherein said fabric is a braid.

7. The device according to claim 6 wherein said braid is a triaxial braid.

8. The device according to claim 7, wherein said braid comprises a monocomponent fiber forming element.

9. The device according to claim 8 wherein said element is a polymer selected from the group consisting of polyethylene terephthalate, polyethylene, polypropylene, polyaramid, polyamide, polyetherether ketone, polyester/polyether block copolymer, liquid crystal polymeric fibers, nylon and carbon.

10. The device according to claim 9 wherein said polymer is preferably polyethylene terephthalate.

11. The device according to claim 7 wherein said braid comprises a bicomponent fiber forming element.

12. The device according to claim 11 wherein said element is a plurality of polymers selected from the group consisting of polyethylene terephthalate, polyeth-

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ylene, polypropylene, polyaramid, polyamide, polyetherether ketone, polyester/polyether block copolymer, liquid crystal polymeric fibers, nylon and carbon.

13. The device according to claim 12 wherein at least one of said polymers is elastomeric.

14. The device according to claim 13 wherein said elastomeric polymer is preferably polyester/polyether block copolymer.

15. The device according to claim 12 wherein said polymers are preferably polyethylene terephthalate and polyester/polyether block copolymer.

16. The device according to claim 1 wherein said suture is lock stitched to said ends.

17. The device according to claim 1 wherein said suture is sewn into said body.

18. The device according to claim 17 wherein said suture is axially oriented in a longitudinal direction.

19. The device according to claim 1 wherein said body is covered with a gel coating.

20. The device according to claim 19 wherein said body and said suture are covered with a gel coating.

21. The device according to claim 20 wherein said coating is a hydrogel selected from the group consisting of sodium alginate, hyaluronic acid, crosslinked hyaluronic acid, crosslinked calcium alginate and a calcium alginate crosslinked hyaluronic acid mixture.

22. The device according to claim 21 wherein said hydrogel is preferably crosslinked calcium alginate.

23. The device according to claim 1 wherein said body defines a polygon.

24. The device according to claim 23 wherein said polygon is a rectangle.

25. The device according to claim 23 wherein at least one of said ends of said body terminates substantially in a point.

26. The device according to claim 25 wherein said point lies along a central axis of said body.

27. The device according to claim 1 wherein said ends are sealed proximate end edges to maintain edge integrity.

28. The device according to claim 1 wherein said body is a flat band triaxial tube.

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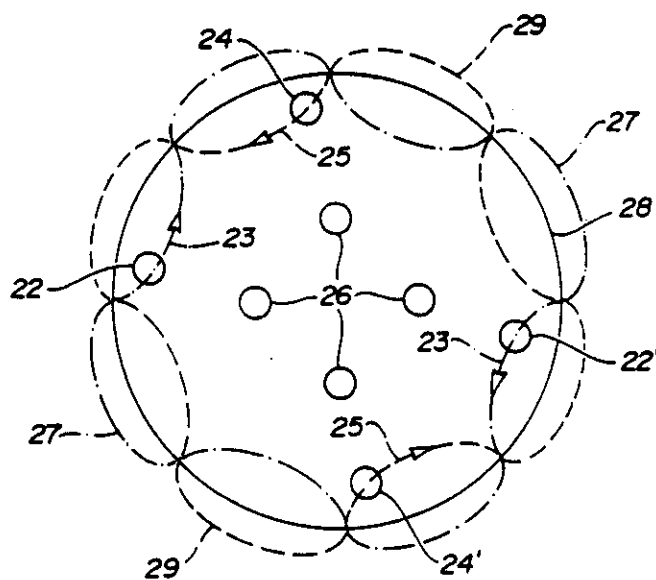
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As Originally Filed

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FIG-1



As Originally Filed

838511

FIG-2

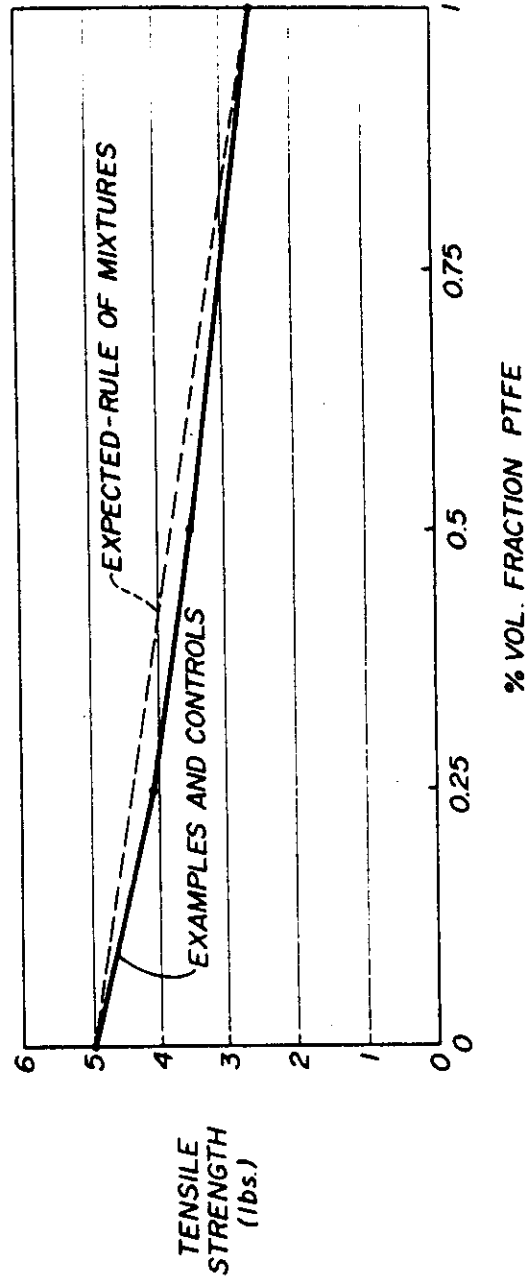
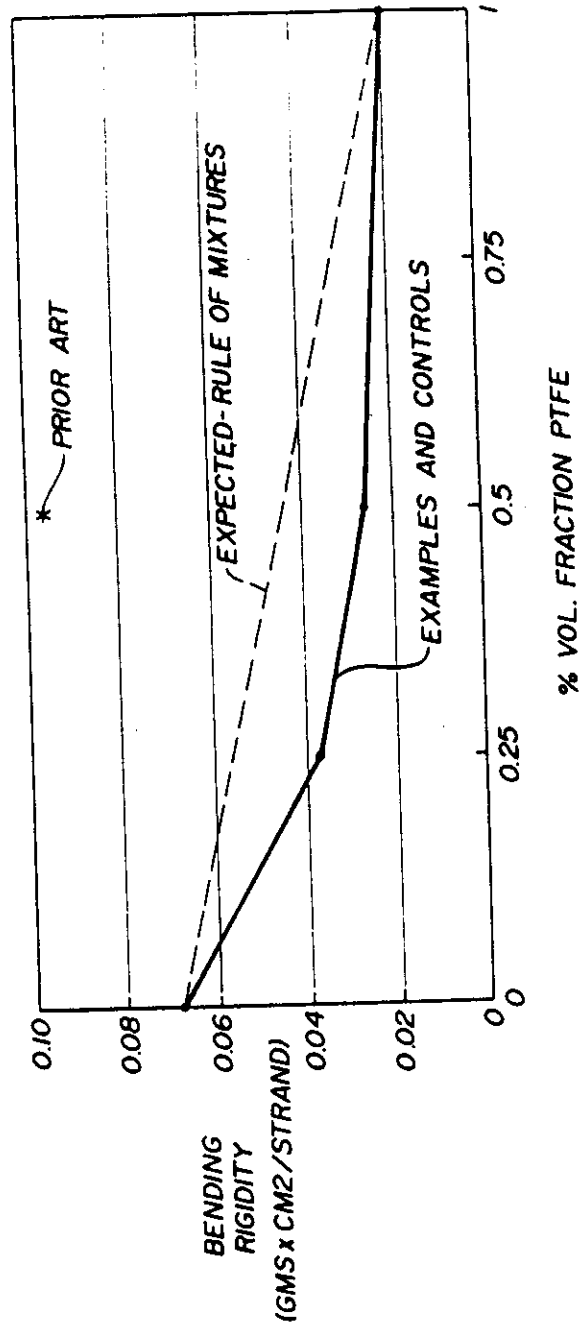


FIG-3



d 11 16

11. 4,959,069, Sep. 25, 1990, Braided surgical sutures; Karl W. Brennan, et al., 606/228; 87/7; 428/224 [IMAGE AVAILABLE]

X 4,470,941, Sep. 11, 1984, Preparation of composite surgical sutures; Leonard D. Kurtz, 264/136, 108, 134, 171, 174, 288.8, 290.5, 345; 606/230

=> d his

(FILE 'USPAT' ENTERED AT 12:54:30 ON 25 JUN 92)

L1 5156 S SUTURE#
L2 8197 S BRAID?
L3 361 S L1 AND L2
L4 2442 S INTERTWIN?
L5 18 S L3 AND L4
L6 103608 S COMPOSITE
L7 (1043648) S S
L8 3 S L5 AND L6
L9 20 S L6(3A)L1

=> d 13 37 57 188

37. 5,059,213, Oct. 22, 1991, Spiroid braided suture; Michael P. Chesterfield, et al., 606/228 [IMAGE AVAILABLE]

57. 5,019,093, May 28, 1991, Braided suture; Donald S. Kaplan, et al., 606/228, 230 [IMAGE AVAILABLE]

X 4,470,941, Sep. 11, 1984, Preparation of composite surgical sutures; Leonard D. Kurtz, 264/136, 108, 134, 171, 174, 288.8, 290.5, 345; 606/230

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d his

(FILE 'USPAT' ENTERED AT 08:07:48 ON 22 OCT 92)

| | |
|-----|--|
| L1 | 6291 S SUTURE# OR LIGATURE# |
| L2 | 8447 S BRAID? |
| L3 | 230 S L1(5A)L2 |
| L4 | 117600 S COMPOSITE OR HETEROGENEOUS |
| L5 | 40 S L4 AND L3 |
| L6 | 9257 S PET OR POLYETHYLENETEREPHTHALATE |
| L7 | 49419 S PTFE OR TEFLON OR POLYTETRAFLUOROETHYLENE OR FLUOROPOLYM |
| ER | |
| L8 | 735 S L6 AND L7 |
| L9 | 5 S L8 AND L5 |
| L10 | 35 S L5 NOT L9 |
| L11 | 1 S L10 AND L6 |
| L12 | 6 S L10 AND L7 |
| L13 | 13 S L2 AND L4 AND L6 AND L7 |

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d 19 1 2 3 4 5

X 4,470,941, Sep. 11, 1984, Preparation of composite surgical sutures; Leonard D. Kurtz, 264/136, 108, 134, 171, 174, 288.8, 290.5, 345; 606/230

2. 4,461,298, Jul. 24, 1984, Composite sutures of silk and hydrophobic thermoplastic elastomers; Shalaby W. Shalaby, et al., 606/231; 528/296 528

3. 4,441,496, Apr. 10, 1984, Copolymers of p-dioxanone and 2,5-morpholinediones and surgical devices formed therefrom having accelerated absorption characteristics; Shalaby W. Shalaby, et al., 606/230; 528/354; 606/231 528 606

4. 4,137,921, Feb. 6, 1979, Addition copolymers of lactide and glycolide and method of preparation; Yuzi Okuzumi, et al., 606/230; 525/411, 420; 528/354; 606/231; 623/1 606 528

5. 4,052,988, Oct. 11, 1977, Synthetic absorbable surgical devices of poly-dioxanone; Namassivaya Doddi, et al., 606/231; 528/354; 623/66 528

=> d 1 2 4 8 13

1. 5,147,400, Sep. 15, 1992, Connective tissue prosthesis; Donald S. Kaplan, et al., 623/13, 1, 11, 66 [IMAGE AVAILABLE] 623

2. 5,116,360, May 26, 1992, Mesh composite graft; Leonard Pinchuk, et al., 623/1, 11, 12 [IMAGE AVAILABLE] 623

4. 4,990,158, Feb. 5, 1991, Synthetic semiabsorbable tubular prosthesis; Donald S. Kaplan, et al., 623/1; 57/225 [IMAGE AVAILABLE] 623

X 4,470,941, Sep. 11, 1984, Preparation of composite surgical sutures; Leonard D. Kurtz, 264/136, 108, 134, 171, 174, 288.8, 290.5, 345; 606/230

13. 3,748,828, Jul. 31, 1973, PROCESS AND APPARATUS FOR FLUID-LIQUID CONTACTING; Simon Lefebvre, 55/2, 29, 70, 73, 90, 93, 122, 233, 240, 300, 481, 527; 261/95, 103 55

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623 4-4004

57 4-5010

606 4-4004

| PATENT APPLICATION FEE DETERMINATION RECORD | | | | | | Application or Docket Number | |
|--|----------------------------------|------------------------------------|---------------|------------|-----------|---|------------|
| Effective December 16, 1991 | | | | | | 838511 | |
| CLAIMS AS FILED - PART I | | | | | | SMALL ENTITY OR OTHER THAN SMALL ENTITY | |
| (Column 1) | | (Column 2) | | (Column 3) | | (Column 4) | |
| FOR | NUMBER FILED | NUMBER EXTRA | | RATE | FEE | OR | RATE |
| BASIC FEE | [REDACTED] | | | [REDACTED] | \$ 345.00 | OR | [REDACTED] |
| TOTAL CLAIMS | 24 | minus 20 = | * | 4 | x \$10 = | OR | x \$20 = |
| INDEPENDENT CLAIMS | 1 | minus 3 = | * | 0 | x 36 = | OR | x 72 = |
| MULTIPLE DEPENDENT CLAIM PRESENT | | | | + 110 = | OR | + 220 = | |
| TOTAL | | | | [REDACTED] | OR | TOTAL | |
| 770 | | | | | | | |
| * If the difference in column 1 is less than zero, enter "0" in column 2 | | | | | | | |
| CLAIMS AS AMENDED - PART II | | | | | | SMALL ENTITY OR OTHER THAN SMALL ENTITY | |
| (Column 1) | | (Column 2) | | (Column 3) | | (Column 4) | |
| AMENDMENT A | CLAIMS REMAINING AFTER AMENDMENT | HIGHEST NUMBER PREVIOUSLY PAID FOR | PRESENT EXTRA | | RATE | ADDITIONAL FEE | OR |
| Total | 24 | Minus | ** | 24 | x \$10 = | OR | x \$20 = |
| Independent | 2 | Minus | *** | 3 | x 36 = | OR | x 72 = |
| FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM | | | | + 110 = | OR | + 220 = | |
| TOTAL | | | | [REDACTED] | OR | TOTAL | |
| ADDIT. FEE | | | | [REDACTED] | | | |
| (Column 1) | | (Column 2) | | (Column 3) | | (Column 4) | |
| AMENDMENT B | CLAIMS REMAINING AFTER AMENDMENT | HIGHEST NUMBER PREVIOUSLY PAID FOR | PRESENT EXTRA | | RATE | ADDITIONAL FEE | OR |
| Total | * | Minus | ** | = | x \$10 = | OR | x \$20 = |
| Independent | * | Minus | *** | = | x 36 = | OR | x 72 = |
| FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM | | | | + 110 = | OR | + 220 = | |
| TOTAL | | | | [REDACTED] | OR | TOTAL | |
| ADDIT. FEE | | | | [REDACTED] | | | |
| (Column 1) | | (Column 2) | | (Column 3) | | (Column 4) | |
| AMENDMENT C | CLAIMS REMAINING AFTER AMENDMENT | HIGHEST NUMBER PREVIOUSLY PAID FOR | PRESENT EXTRA | | RATE | ADDITIONAL FEE | OR |
| Total | * | Minus | ** | = | x \$10 = | OR | x \$20 = |
| Independent | * | Minus | *** | = | x 36 = | OR | x 72 = |
| FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM | | | | + 110 = | OR | + 220 = | |
| TOTAL | | | | [REDACTED] | OR | TOTAL | |
| ADDIT. FEE | | | | [REDACTED] | | | |

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
 ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
 *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
 The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Form PTO-875
(Rev. 12-91)

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI000330

| STAPLE | | AREA | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| U.S. GOVERNMENT PRINTING OFFICE: 1991-294-566 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| PATENT NUMBER

APPLICATION SERIAL NUMBER
07/838,511

APPLICANT'S NAME (PLEASE PRINT)
Hunter et al.

IF REISSUE, ORIGINAL PATENT NUMBER

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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
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| 606 | 230 | 6/25/92 | CWR |
| 606 | 231 | 6/25/92 | CWR |
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228 | 8/26/92 | CWR |
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| EXAMINER | 719 | 7-4-92 |
| REVIEWER | 291 | 3-5-98 |
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SYMBOL

✓ Reported

✗ Allowed

• (Through natural) Cancelled

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DePuy Mitek, Inc. v. Arthrex, Inc.
 C.A. No. 04-12457 PBS
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1. Application _____ papers.

2. *Letter Out*

3. *Ref 3-3000*

4. *Request for Recd*

5. *Ref 3-3000*

6. *Request for Recd*

7. *Ref 3-3000*

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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI000335

COVERING COVER 1-800-366-5560
S/8 CUSC PTC 1683.4 100 22.8 150 800000

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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| DePuy Mitek, Inc. |) | |
| |) | |
| |) | |
| Plaintiff, |) | |
| |) | |
| vs. |) | Case No. 04-12457 PBS |
| |) | |
| Arthrex, Inc., |) | |
| |) | |
| Defendant. |) | |
| _____ |) | |

**ARTHREX, INC.'S ANSWER AND COUNTERCLAIM IN RESPONSE
TO DEPUY MITEK, INC.'S AMENDED COMPLAINT**

Defendant Arthrex, Inc. ("Arthrex") responds to the Amended Complaint filed by Plaintiff DePuy Mitek, Inc. ("DePuy Mitek") as follows:

Parties, Jurisdiction and Venue

1. The Complaint purports to bring an action for patent infringement. The remaining allegations of paragraph 1 assert legal conclusions that do not require a response.

2. Admitted.

3. Admitted.

4. Arthrex has insufficient information to admit or deny the allegations of paragraph 4 and therefore denies those allegations.

Answer to Depuy Mitek's Claim for Relief

5. Arthrex admits that U.S. Patent No. 5,314,446 ("the '446 patent") entitled "Sterilized Heterogeneous Braids" is attached as Exhibit A to the Complaint,

and that it issued on May 24, 1994 listing Ethicon as the assignee on the cover page. Arthrex has no knowledge or information sufficient to confirm whether Ethicon, Inc. assigned the '446 patent to DePuy Mitek and therefore denies the same. Arthrex denies that the patent was duly and legally issued by the U.S. Patent and Trademark Office.

6. Arthrex admits that it sells sutures under the trade name FiberWire™ in the United States, including within this judicial district, but denies each and every other allegation contained in paragraph 6 of the Amended Complaint.

7. Arthrex denies each and every allegation contained in paragraph 7 of the Amended Complaint.

8. Arthrex admits that it was involved in the design, development and commercialization of FiberWire™ and TigerWire® sutures and that at least some of those products would be sold in the United States. Arthrex denies the remaining allegations of paragraph 8 of the Amended Complaint.

9. Arthrex denies each and every allegation contained in paragraph 9 of the Amended Complaint.

10. Arthrex has insufficient information to admit or deny the allegations of paragraph 10 and therefore denies those allegations.

11. Arthrex denies each and every allegation contained in paragraph 11 of the Amended Complaint.

FURTHER ANSWERING, Arthrex presents the following affirmative defenses:

AFFIRMATIVE DEFENSES

12. The '446 patent is invalid under 35 U.S.C. § 102.

13. The '446 patent is invalid under 35 U.S.C. § 103.

14. The '446 patent is invalid under 35 U.S.C. § 112.

15. Arthrex does not now infringe and has not infringed the '446 patent either literally or under the doctrine of equivalents.

16. Arthrex does not now induce and has not induced others to infringe the '446 patent either literally or under the doctrine of equivalents.

17. By virtue of DePuy Mitek's unreasonable and unjustified delay in bringing the present lawsuit to the prejudice of Arthrex, recovery is barred under the doctrine of laches.

18. Upon information and belief, the '446 patent is unenforceable due to inequitable conduct committed before the U.S. Patent and Trademark Office ("the Patent Office") during prosecution of the application which eventually issued as the '446 patent for the following reasons, among others.

19. During prosecution of U.S. Application No. 838,511 ("the '511 application"), which eventually issued as the '446 patent, the applicants and their attorneys mischaracterized and misrepresented the disclosure of U.S. Patent No. 5,147,400 to Kaplan et al. ("Kaplan") in distinguishing Kaplan from the claims of the '511 application. For example, in response to rejections on anticipation and obviousness grounds under 35 U.S.C. §§ 102, 103, on August 4, 1993, the applicants and their attorneys falsely represented that the sheath yarn component of Kaplan always contains at least in part, a bio-absorbable portion and that Kaplan teaches away from a combination of non-bio-absorbable yarns. Kaplan, however, does not always contain a bio-absorbable portion and discloses a combination of non-bio-absorbable yarns.

20. During the prosecution of the '511 application, applicants and their attorneys responded to a rejection based on U.K. Patent Application No. 2,218,312A to Burgess ("Burgess") by stating in a response, filed on August 6, 1992, that the use of a high tensile polythene thread in a braided construction would have poor qualities for a

suture and that a designer using such materials for a suture would inevitably design an unacceptable suture. If applicants and their attorneys believed that high tensile polythene was included within their claimed invention, then they could not have truthfully made these statements and representations to the examiner.

21. The applicants and their attorneys acted with intent to deceive the Patent Office since they knew or should have known that their statements were false and misleading and that the Patent Office would rely on such statements in reconsidering the rejections in light of Kaplan and Burgess. In fact, following the applicants' and their attorneys' misrepresentations and mischaracterizations of Kaplan and Burgess, the '511 application was allowed and eventually issued as the '446 patent.

22. DePuy Mitek, by virtue of its efforts to obtain, enforce and use the '446 patent, knowing said patent to be invalid, unenfringed, and unenforceable, have misused said patent, whereby DePuy Mitek is precluded from enforcing the same against Arthrex.

COUNTERCLAIM

1. Arthrex, is a corporation organized under the laws of the State of Delaware, with its corporate headquarters and principal place of business at 1370 Creekside Boulevard, Naples, Florida 34108.

2. DePuy Mitek is a corporation organized under the laws of the State of Massachusetts, with its corporate headquarters and principal place of business at 249 Vanderbilt Avenue, Norwood, Massachusetts 02062.

3. Arthrex repeats and realleges and incorporates herein by reference, paragraphs 12-22 of its Affirmative Defenses.

4. This is a claim arising under the Patent Laws of the United States, Title 35, United States Code, for a declaratory judgment under 28 U.S.C. §§ 2201 and 2202. The jurisdiction of this Court is founded upon 28 U.S.C. §§ 1338(a), 2201 and 2202.

5. DePuy Mitek alleges that it is the owner of the '446 patent. There exists an actual controversy between Arthrex and DePuy Mitek with respect to the validity, enforceability, scope and infringement of the '446 patent.

6. The '446 patent is not infringed, and further is invalid and unenforceable at least for the reasons set forth in paragraphs 12-22 of Arthrex's Affirmative Defenses.

7. Arthrex seeks a declaration by the Court that the '446 patent is not infringed, either directly or by inducement, by Arthrex, that the '446 patent is invalid and unenforceable, and that DePuy Mitek, knowing that the '446 patent is invalid, not infringed by Arthrex and unenforceable, while asserting the patent against Arthrex, has committed patent misuse.

8. DePuy Mitek's conduct renders this an exceptional case within the provisions of 35 U.S.C. § 285, and Arthrex is accordingly entitled to an award of attorneys' fees.

WHEREFORE, Arthrex prays for judgment against DePuy Mitek as follows:

A. That the Court deny all relief to DePuy Mitek, and that the Amended Complaint be dismissed with prejudice;

B. That the Court decree, adjudge and declare that the '446 patent is invalid, not infringed by Arthrex, directly or through inducement, and unenforceable and that DePuy Mitek has committed patent misuse by knowingly asserting an invalid

and unenforceable patent against Arthrex, with knowledge that Arthrex does not infringe said patent;

C. That the Court find this an exceptional case and award reasonable attorney fees to Arthrex under 35 U.S.C. § 285;

D. That the Court award Arthrex its costs, and expenses; and

E. That the Court grant such further relief as it deems just and proper.

JURY DEMAND

Arthrex demands a trial by jury on all issues triable to a jury with respect to its counterclaim.

Dated: September 26, 2005

Respectfully submitted,

By: s/Charles W. Saber

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Counsel for Defendant
Arthrex, Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Arthrex, Inc.'s Answer and Counterclaim in Response to DePuy Mitek, Inc.'s Amended Complaint was served via overnight courier on September 26, 2005, upon the following counsel for DePuy Mitek, Inc.:

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s/Salvatore P. Tamburo

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.

Plaintiff,

vs.

Arthrex, Inc.,

Defendant.

Case No. 04-12457 PBS

**PEARSALLS LIMITED'S ANSWER AND COUNTERCLAIM IN RESPONSE
TO DEPUY MITEK, INC.'S AMENDED COMPLAINT**

Defendant Pearsalls Limited ("Pearsalls") responds to the Amended Complaint filed by Plaintiff DePuy Mitek, Inc. ("DePuy Mitek") as follows:

Parties, Jurisdiction and Venue

1. The Complaint purports to bring an action for patent infringement. The remaining allegations of paragraph 1 assert legal conclusions that do not require a response.

2. Admitted.

3. Admitted.

4. Admitted.

Answer to Depuy Mitek's Claim for Relief

5. Pearsalls admits that U.S. Patent No. 5,314,446 ("the '446 patent") entitled "Sterilized Heterogeneous Braids" is attached as Exhibit A to the Complaint, and that it issued on May 24, 1994 listing Ethicon as the assignee on the cover page.

Pearsalls has no knowledge or information sufficient to confirm whether Ethicon, Inc. assigned the '446 patent to DePuy Mitek and therefore denies the same. Pearsalls denies that the patent was duly and legally issued by the U.S. Patent and Trademark Office.

6. Pearsalls admits that Arthrex sells sutures under the trade name FiberWire™ in the United States, including within this judicial district, but denies each and every other allegation contained in paragraph 6 of the Amended Complaint.

7. Pearsalls denies each and every allegation contained in paragraph 7 of the Amended Complaint.

8. Pearsalls admits that it was involved in the design, development and commercialization of FiberWire™ and TigerWire® sutures and that at least some of those products would be sold in the United States. Pearsalls denies the remaining allegations of paragraph 8 of the Amended Complaint.

9. Pearsalls has insufficient information to admit or deny the allegations of the first sentence of paragraph 9 and therefore denies those allegations. Pearsalls denies the remaining allegations of paragraph 9.

10. Pearsalls admits the allegations of paragraph 10 of the Amended Complaint.

11. Pearsalls denies each and every allegation contained in paragraph 11 of the Amended Complaint.

FURTHER ANSWERING, Pearsalls presents the following affirmative defenses:

AFFIRMATIVE DEFENSES

12. The Court lacks personal jurisdiction over Pearsalls since Pearsalls does not reside within this judicial district and DePuy Mitek has failed to allege that Pearsalls engages in business activity within this judicial district sufficient to vest this Court with personal jurisdiction over Pearsalls.

13. Service was insufficient because, upon information and belief, service of process was not performed in compliance with Rule 4(f) of the Federal Rules of Civil Procedure.

14. The '446 patent is invalid under 35 U.S.C. § 102.

15. The '446 patent is invalid under 35 U.S.C. § 103.

16. The '446 patent is invalid under 35 U.S.C. § 112.

17. Pearsalls does not now infringe and has not infringed the '446 patent either literally or under the doctrine of equivalents.

18. Pearsalls does not now induce and has not induced others to infringe the '446 patent either literally or under the doctrine of equivalents.

19. Upon information and belief, the '446 patent is unenforceable due to inequitable conduct committed before the U.S. Patent and Trademark Office ("the Patent Office") during prosecution of the application which eventually issued as the '446 patent for the following reasons, among others.

20. During prosecution of U.S. Application No. 838,511 ("the '511 application"), which eventually issued as the '446 patent, the applicants and their attorneys mischaracterized and misrepresented the disclosure of U.S. Patent No. 5,147,400 to Kaplan et al. ("Kaplan") in distinguishing Kaplan from the claims of the '511 application. For example, in response to rejections on anticipation and obviousness

grounds under 35 U.S.C. §§ 102, 103, on August 4, 1993, the applicants and their attorneys falsely represented that the sheath yarn component of Kaplan always contains at least in part, a bio-absorbable portion and that Kaplan teaches away from a combination of non-bio-absorbable yarns. Kaplan, however, does not always contain a bio-absorbable portion and discloses a combination of non-bio-absorbable yarns.

21. During the prosecution of the '511 application, applicants and their attorneys responded to a rejection based on U.K. Patent Application No. 2,218,312A to Burgess ("Burgess") by stating in a response, filed on August 6, 1992, that the use of a high tensile polythene thread in a braided construction would have poor qualities for a suture and that a designer using such materials for a suture would inevitably design an unacceptable suture. If applicants and their attorneys believed that high tensile polythene was included within their claimed invention, then they could not have truthfully made these statements and representations to the examiner.

22. The applicants and their attorneys acted with intent to deceive the Patent Office since they knew or should have known that their statements were false and misleading and that the Patent Office would rely on such statements in reconsidering the rejections in light of Kaplan and Burgess. In fact, following the applicants' and their attorneys' misrepresentations and mischaracterizations of Kaplan and Burgess, the '511 application was allowed and eventually issued as the '446 patent.

23. DePuy Mitek, by virtue of its efforts to obtain, enforce and use the '446 patent, knowing said patent to be invalid, unenforced, and unenforceable, have misused said patent, whereby DePuy Mitek is precluded from enforcing the same against Pearsalls.

COUNTERCLAIM

1. Pearsalls is a private limited company organized under the laws of the United Kingdom with a principal place of business at Tancred Street, Taunton, Somerset TA1 1RY.

2. DePuy Mitek is a corporation organized under the laws of the State of Massachusetts, with its corporate headquarters and principal place of business at 249 Vanderbilt Avenue, Norwood, Massachusetts 02062.

3. Pearsalls repeats and realleges and incorporates herein by reference, paragraphs 12-23 of its Affirmative Defenses.

4. This is a claim arising under the Patent Laws of the United States, Title 35, United States Code, for a declaratory judgment under 28 U.S.C. §§ 2201 and 2202. The jurisdiction of this Court is founded upon 28 U.S.C. §§ 1338(a), 2201 and 2202.

5. DePuy Mitek alleges that it is the owner of the '446 patent. There exists an actual controversy between Pearsalls and DePuy Mitek with respect to the validity, enforceability, scope and infringement of the '446 patent.

6. The '446 patent is not infringed, and further is invalid and unenforceable at least for the reasons set forth in paragraphs 14-23 of Pearsalls' Affirmative Defenses.

7. Pearsalls seeks a declaration by the Court that the '446 patent is not infringed, either directly or by inducement, by Pearsalls, that the '446 patent is invalid and unenforceable, and that DePuy Mitek, knowing that the '446 patent is invalid, not infringed by Pearsalls and unenforceable, while asserting the patent against Pearsalls, has committed patent misuse.

8. DePuy Mitek's conduct renders this an exceptional case within the provisions of 35 U.S.C. § 285, and Pearsalls is accordingly entitled to an award of attorneys' fees.

WHEREFORE, Pearsalls prays for judgment against DePuy Mitek as follows:

A. That the Court deny all relief to DePuy Mitek, and that the Amended Complaint be dismissed with prejudice;

B. That the Court decree, adjudge and declare that the '446 patent is invalid, not infringed by Pearsalls, directly or through inducement, and unenforceable and that DePuy Mitek has committed patent misuse by knowingly asserting an invalid and unenforceable patent against Pearsalls, with knowledge that Pearsalls does not infringe said patent;

C. That the Court find this an exceptional case and award reasonable attorney fees to Pearsalls under 35 U.S.C. § 285;

D. That the Court award Pearsalls its costs, and expenses; and

E. That the Court grant such further relief as it deems just and proper.

JURY DEMAND

Pearsalls demands a trial by jury on all issues triable to a jury with respect to its counterclaim.

Dated: October 14, 2005

Respectfully submitted,

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Counsel for Defendants
Arthrex, Inc. and Pearsalls Limited

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Pearsalls Limited's Answer and Counterclaim in Response to DePuy Mitek, Inc.'s Amended Complaint was electronically filed with the Court and served via the Court's email notification service on October 14, 2005, upon the following counsel for DePuy Mitek, Inc.:

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s/Salvatore P. Tamburo

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

**ARTHREX, INC.'S SECOND SUPPLEMENTAL OBJECTIONS AND RESPONSES
TO DEPUY MITEK, INC.'S INTERROGATORY NOS. 3, 5, AND 7 AND
ARTHREX'S SUPPLEMENTAL OBJECTIONS AND RESPONSE TO DEPUY
MITEK, INC.'S INTERROGATORY NO. 6**

Pursuant to Rule 33 of the Federal Rules of Civil Procedure and Rule 33.1 of the Local Rules of the United States District Court for the District of Massachusetts, Defendant Arthrex, Inc., ("Arthrex") hereby provides second supplemental responses to Defendant DePuy Mitek, Inc.'s ("DePuy Mitek's") Interrogatory Nos. 3, 5, and 7 of DePuy Mitek's First Set of Interrogatories and supplemental response to Defendant DePuy Mitek, Inc.'s ("DePuy Mitek's") Interrogatory No. 6 of DePuy Mitek's First Set of Interrogatories. These supplemental responses are based on information reasonably available to Arthrex at the present time. Arthrex reserves the right to further supplement these responses when, and if, additional information becomes available, or known, to Arthrex. These interrogatories also remain premature to the extent that they

seek expert information. Such information will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement filed by the parties and Scheduling Order entered by the Court. Arthrex also reserves the right to object on any ground at any time to these Interrogatories. Arthrex further reserves the right to object on any ground to such other or supplemental Interrogatories DePuy Mitek may propound involving or relating to the subject matter of these Interrogatories.

GENERAL OBJECTIONS

Arthrex incorporates herein the General Objections included in its Objections and Answers to DePuy Mitek's First Set of Interrogatories as if fully set forth herein.

DEFINITIONS

Arthrex incorporates herein the Definitions included in its Objections and Answers to DePuy Mitek's First Set of Interrogatories as if fully set forth herein.

ANSWERS AND SPECIFIC OBJECTIONS

The following Second Supplemental Responses to DePuy Mitek's Interrogatory Nos. 3, 5, and 7 and Supplemental Response to DePuy Mitek's Interrogatory No. 6 are made subject to and without waiver of the foregoing General Objections, and such General Objections are incorporated into each Response as though fully set forth therein. To the extent particular General Objections are restated in a Response, they are provided because they are particularly applicable to the specific Interrogatory and such inclusion is not to be construed as a waiver of any other General Objections.

INTERROGATORY NO. 3.

Describe all facts that support Arthrex's contentions that it has not infringed any claim of the Patent-in-Suit as set forth in ¶¶ 12-13 of Arthrex's Answer including, but not limited to,

(a) identifying each element of each claim of the Patent-in-Suit that Arthrex contends is literally absent from each Arthrex Braided Suture Product;

(b) explain (i) what Arthrex contends the basic and novel characteristics of the invention claimed in the Patent-in-Suit are; (ii) each contention that Arthrex does not infringe the Patent-in-Suit because its Braided Suture Products have a material that materially affects the claims' basic and novel characteristics; and (iii) what the material effect on the claims' basic and novel characteristics are by an alleged material in Arthrex's Braided Suture Products.

(c) explain any Arthrex contention that any alleged absent claim element is not satisfied under the doctrine of equivalents by describing all alleged substantial differences between the claim and Arthrex's Braided Suture Products and any reason why the function/way/result test is not satisfied for each Arthrex Braided Suture Product; and

example, Burgess in view of either one of U.S. Patent Nos. 4,563,392 or 4,543,286, both to Harpell et al. ("the Harpell patents"). Both of the Harpell patents disclose the use of UHMWPE in surgical suture applications. Had the Examiner known of the Harpell patents in August 1992, he would have maintained the rejection of claims 1 and 8 on § 103 grounds.

Claims 2 and 12 of the '446 patent would also be invalid under § 103 as being unpatentable over Burgess and the Harpell patents in view of the state of the art at the time of the alleged invention as disclosed in, for example, the '011 patent. '011 patent at FIG. 1.

The above is not intended to be an exhaustive list of reasons why the '446 patent is invalid under 35 U.S.C. §§ 102, 103, but rather, it is intended to be only an exemplary list of such reasons.

INTERROGATORY NO. 6.

With respect to Arthrex's inequitable conduct defense and counterclaim:

- (a) identify all persons who allegedly committed inequitable conduct;
- (b) state all facts supporting Arthrex's contention that the such persons committed inequitable conduct; and
- (c) identify each piece of information that was allegedly withheld and each alleged misrepresentation and why the alleged withheld information or misrepresentation is material.

RESPONSE

Arthrex objects to this Interrogatory to the extent that it seeks information not yet in Arthrex's possession. Most of the facts surrounding the alleged inequitable conduct are known to the applicants of U.S. Application No. 838,511 ("the '511 application"), which eventually issued as the '446 patent, and their attorneys; and since discovery has

only just begun in this case, Arthrex has not yet had an opportunity to obtain all information responsive to this Interrogatory. Subject to and without waiving its general and specific objections, Arthrex answers:

(a) At least the applicants of the '511 application and their attorneys, including Hal Brent Woodrow, committed the alleged inequitable conduct.

(b) During prosecution of the '511 application, the applicants and their attorneys mischaracterized and misrepresented the disclosure of U.S. Patent No. 5,147,400 to Kaplan et al. ("Kaplan") in distinguishing Kaplan from claim 21 of the '511 application. For example, in response to rejections on anticipation and obviousness grounds under 35 U.S.C. §§ 102, 103, on August 4, 1993, the applicants and their attorneys falsely represented that the sheath yarn component of Kaplan always contains at least in part, a bio-absorbable portion and that Kaplan teaches away from a combination of non-bioabsorbable yarns.

The applicants and their attorneys misrepresented Kaplan as stating "in one embodiment, the sheath yarn could also contain a non-bioabsorbable yarn of one or more chemical composition." See Amendment filed August 4, 1993 at page 2. The applicants and their attorneys then immediately went on to state that claim 21 does not claim a sheath yarn composed of a bio-absorbable yarn. *Id.*

Their statements regarding Kaplan's teachings were entirely misleading, however. Kaplan actually states that "sheath component 34 may also be fabricated from individual filaments *having more than two different chemical compositions, one or more of which optionally being non-bioabsorbable.*" [Emphasis added.] Kaplan at column 9, lines 25-28. In other words, Kaplan discloses that the sheath component may be fabricated from individual filaments, all of which may be non-bioabsorbable.

The applicants and their attorney again misrepresented the teachings of Kaplan when they stated that "the sheath, however, may optionally have, in addition to the bioabsorbable sheath yarn, one or more non-bioabsorbable filaments." See Amendment

filed August 4, 1993 at page 3. As described above, Kaplan does, in fact, disclose a sheath containing all non-bioabsorbable yarns.

(c) The mischaracterizations and misrepresentations made by the applicants and their attorneys were material since the Examiner ostensibly relied on them in deciding that the rejections based on Kaplan had been overcome and in allowing the '511 application after the Amendment was filed on August 4, 1993.

SUPPLEMENTAL RESPONSE

In addition to the above, Arthrex further responds that during the prosecution of the '511 application, applicants and their attorney, Matthew S. Goodwin, responded to a rejection based on U.K. Patent Application No. 2,218,312A to Burgess ("Burgess") by stating in a response, filed on August 6, 1992, that the use of a high tensile polythene thread in a braided construction, with polyester and/or nylon, would have poor qualities for a suture (e.g., poor knot strength, poor knot security, low elongation and poor knot sliding) and that a designer using such materials for a suture would inevitably design an unacceptable suture. If applicants and their attorneys truly believed that high tensile polythene was included within their claimed invention, then they could not have honestly made these statements and representations to the examiner. Accordingly, in such circumstances, the applicants and their attorney made a material misstatement with intent to deceive the PTO.

INTERROGATORY NO. 7.

With respect to Arthrex's contentions that the asserted claims are invalid under 35 U.S.C. § 112 (Answer at Affirmative defenses ¶11):

(a) identify each claim of the Patent-in-Suit that is allegedly invalid under 35 U.S.C. § 112; and

Dated: January 27, 2006

By: s/Charles W. Saber

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Counsel for Defendants Arthrex, Inc.
and Pearsalls, Limited

CERTIFICATE OF SERVICE

It is hereby certified that a true and correct copy of the foregoing Arthrex, Inc.'s Second Supplemental Objections and Responses to DePuy Mitek, Inc.'s Interrogatory Nos. 3, 5 and 7 and Supplemental Objections and Response to DePuy Mitek, Inc.'s Interrogatory No. 6 has been served by facsimile on the following counsel for DePuy Mitek, Inc. on this 27th day of January 2006:

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s/Salvatore P. Tamburo
Salvatore P. Tamburo

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

EXPERT REPORT OF JOHN F. WITHERSPOON

INTRODUCTION

I have been asked by counsel for defendant Arthrex, Inc. (“Arthrex”) to serve as an expert consultant with respect to United States patent practices and procedures, both generally and as they relate to this case, and on various issues in the case. I understand that I may be called to present expert testimony at trial, including testimony in rebuttal, and I have been asked to prepare a written report with respect to that possible testimony. More specifically, I have been asked at this time to prepare a report setting forth (a) a general description of United States Patent and Trademark Office (“PTO”) practices and procedures, (b) a discussion of the prosecution history of United States Patent No. 5,314,446 (“the ‘446 patent”) here in suit, and (c) opinions specific to this case regarding certain issues for which Arthrex has the burden of proof.

I reserve the right to file a report in rebuttal to those filed on behalf of the plaintiff. I also reserve the right to supplement my report(s) so as to accommodate the discovery of any additional information that may impact my testimony and opinions.

BACKGROUND AND PROFESSIONAL EXPERIENCE

1. I am a citizen of the United States and reside in Bethesda, Maryland.
2. I am an attorney in private practice in Washington, D.C., where I have practiced patent law for over thirty years. In addition, I served as an Examiner-in-Chief (a position now called “Administrative Patent Judge”) and as a member of the Board of Appeals (now named the Board of Patent Appeals and Interferences) in the PTO for seven and one-half years. Before entering private practice, I served for two years as a Law Clerk to Judge Giles Sutherland Rich of the United States Court of Customs and Patent Appeals (“CCPA”) a predecessor court to the United States Court of Appeals for the Federal Circuit (“Federal Circuit”).
3. From 1992-2004, I was Distinguished Professor of Intellectual Property Law and Coordinator or Co-Director of the specialty track in Intellectual Property Law at George Mason University School of Law in Arlington, Virginia, where I was a member of the part-time faculty and taught courses in patent law. In recognition of this work the law school faculty and University Provost unanimously voted to accord me the title “Professor and Director Emeritus, Intellectual Property Program, George Mason University School of Law.” From 1998-2000, I also served as an Adjunct Professor of Law at the Georgetown University Law Center in Washington, D.C.
4. I was nominated by the President of the United States and confirmed by the Senate to be an Examiner-in-Chief and a member of the then Board of Appeals of the

PTO. The Board of Appeals is a review tribunal within the PTO that by statute sits in panels of at least three members to hear appeals from adverse decisions of examiners. It reviews the record made during the examination of an application, receives briefs from counsel and examiners, conducts hearings, and prepares written opinions. The Board's decisions constitute final agency determinations with respect to substantive questions of patent law. They are reviewable only by the Federal Circuit or by the United States District Court for the District of Columbia, whose decisions in such cases are in turn reviewable by the Federal Circuit. My work as a member of the Board of Appeals required an understanding of patent specifications, including patent claims and how they should be construed, as well as an understanding and application of the pertinent statutes, precedents, rules, and other regulations regarding the requirements for patentability and the examination of patent applications for issuance of United States letters patents. While on the Board, I participated in deciding more than 1,500 appeals.

5. During my career in private practice, I have personally prosecuted hundreds of applications for patents and reviewed hundreds of prosecution histories of other applications. As part of this work, I have had occasion to review thousands of claims in patents and patent applications to determine their meaning, to compare them with the prior art and other claims, to compare them with patent specifications, or to compare them with accused products, processes, etc. For the past twenty-five years I have also served as a consulting and/or testifying expert in patent litigation.

6. I am admitted to practice law in the District of Columbia and before the Supreme Court of the United States, the United States Court of Appeals for the District of

Columbia Circuit and the United States Court of Appeals for the Federal Circuit. I am also registered to practice before the PTO.

7. I am a member of numerous bar associations and professional societies relating to patent law and to science, including the American Bar Association Section of Intellectual Property Law, the American Intellectual Property Law Association, the Federal Circuit Bar Association, the Patent and Trademark Office Society, the Giles Sutherland Rich American Inn of Court, the New York Intellectual Property Law Association, the American Association for the Advancement of Science, and the American Chemical Society. Over the years I have held leadership positions in a number of these organizations.

8. I have been a member of the Advisory Board of BNA's Patent, Trademark and Copyright Journal since 1979. I am the editor of a book by BNA entitled "Nonobviousness—The Ultimate Condition of Patentability," and I have written several published articles in the field of United States patent law and practice. In addition, I have presented lectures and speeches about United States patent law and practice throughout the United States and Europe, including to the Judicial Conferences of the CCPA and the Federal Circuit.

9. I did undergraduate and graduate studies at the University of Illinois, receiving a B.S. degree in 1955, an M.Ed. degree in 1958, and an M.S. degree in Chemistry in 1960. I received an L.L.B. degree (later changed to a J.D. degree) from Georgetown University Law Center in 1964.

10. A copy of my Curriculum Vitae, which lists my publications, and a listing of cases in which I have testified in the past four years are attached as Exhibits A and B, respectively.

DATA AND OTHER INFORMATION CONSIDERED

11. In preparing this report, I reviewed the following materials:

- a) U.S. Patent No. 5,314,446 in the names of Alastair W. Hunter, Arthur Taylor, Jr. and Mark Steckel ("the '446 patent");
- b) Prosecution history of the '446 patent;
- c) U.S. Patent Nos. 4,543,286 ("Harpell *et al.* '286"); 4,563,392 ("Harpell *et al.* '392"); 4,610,688 ("Silvestrini *et al.*"); 5,120,802 ("Mares *et al.*"); and 5,318,575 ("Chesterfield *et al.*");
- d) U.K. Patent Application 2 218 312 A ("Burgess");
- e) Brochure designated Dyneema SK60 ("the Dyneema brochure") (Bates Nos. PR 08420-429);
- f) Article by Cohan *et al.* entitled "An Evaluation of Ultrastrong Polyethylene Fiber as an Ophthalmic Suture" ("Cohan *et al.*") (Bates Nos. ARM 25132-137);
- g) DePuy Mitek's Responses to Arthrex, Inc.'s First Set of Interrogatories; DePuy Mitek's Supplemental Responses to Arthrex, Inc.'s First Set of Interrogatories; DePuy Mitek's Responses to Arthrex, Inc.'s Second Set of Interrogatories; DePuy Mitek's Second Supplemental Responses to Arthrex, Inc.'s First Set of Interrogatories; and DePuy Mitek's Second Supplemental Responses to Arthrex, Inc.'s Interrogatory No. 15;
- h) Arthrex, Inc.'s Objections and Answers to DePuy Mitek, Inc.'s First Set of Interrogatories; Arthrex, Inc.'s Supplemental Objections and Responses to DePuy Mitek, Inc.'s Interrogatory Nos. 2, 4, 10 and 12; Arthrex, Inc.'s Supplemental Objections and Responses to DePuy Mitek, Inc.'s Interrogatory Nos. 3, 5 and 7; Arthrex, Inc.'s Supplemental Objections and Response to DePuy Mitek, Inc.'s Interrogatory No. 1; Arthrex, Inc.'s Second Supplemental Objections and Responses to DePuy Mitek, Inc.'s Interrogatory Nos. 3, 5, and 7 and Arthrex's Supplemental Objections and Response to DePuy Mitek, Inc.'s Interrogatory No. 6; Arthrex, Inc.'s Objections and Response to DePuy Mitek, Inc.'s Second Set of Interrogatories to Arthrex, Inc.; and Pearsalls, Limited's

Objections and Response to DePuy Mitek, Inc.'s Second Set of Interrogatories to Pearsalls, Limited;

- i) Transcripts of depositions of Dr. Mark G. Steckel given on January 26 and January 27, 2006; Dennis J. Jamiolkowski given on November 30, 2005; Hal Brent Woodrow given on November 2, 2005; and Matthew Goodwin given on January 17, 2006;
- j) Portions of laboratory Book No. 2175, issued to Mark Steckel (Bates Nos. DMI002605-2678);
- k) Documents bearing Bates Nos. DMI095015-5042;
- l) Five page document entitled DePuy Mitek's Privileged Document List, dated January 23, 2006;
- m) Discussion with Dr. Debi Prasad Mukherjee; and
- n) Expert Report of Dr. Debi Prasad Mukherjee Concerning Invalidity of U.S. Patent No. 5,314,446.

BASES FOR TESTIMONY AND OPINIONS

12. The bases for my testimony and opinions are the materials identified above; my background, training, and over forty-three years of working experience in the field of patent law and practice, including my knowledge of and experience with the practices and procedures of the PTO, acquired in part during the more than seven years that I served as a member of the PTO Board of Appeals; the patent statutes; case decisions; the PTO rules of practice as set forth in Title 37 of the Code of Federal Regulations (37 CFR); and the PTO Manual of Patent Examining Procedure ("MPEP"). My testimony may also be based, in part, on the testimony and discussions with other witnesses (both expert and fact) and associated documentation in this case.

GENERAL CONSIDERATIONS

The Parts of Patent Applications and Patents

13. A patent is a legal document issued by the federal government that reflects a kind of bargain between an inventor and the public. The inventor must have made an invention that satisfies certain legal requirements and must disclose the invention in accordance with certain legal standards. The public, in turn, grants to the patent owner the right to exclude others from practicing the invention during the term of the patent. Contrary to popular belief, a patent does not grant to the patent owner the right to practice the invention.

14. Patents are directed to one of four statutory classes of subject matter that qualifies for patent protection—(1) process, (2) machine, (3) manufacture, and (4) composition of matter. Thus, also contrary to popular belief, patents do not protect concepts or ideas. Rather, they pertain to the “useful arts”—the term used in the Constitution.

15. A patent or patent application consists of two main parts: a “written description” and one or more “claims.” The two parts constitute the *quid* and the *quo* of the bargain.

16. The written description, sometimes called the specification, explains what the invention is, how it is made, how it is used, and the best mode of carrying out the invention, all in sufficient detail that the public (*i.e.*, persons skilled in the art to which the invention pertains) is able to understand and practice the invention without undue experimentation. Drawings, charts and/or graphs are often used to help explain what is

being described. The “written description” part of a patent is basically a teaching document. Its purpose is to satisfy the inventor’s part of the bargain with the public.

17. In contrast, the claims of a patent are legal instruments that define the scope of the patent owner’s exclusive rights. Each claim is a separate instrument. It is a single sentence comprising a list of words and phrases (known as claim “elements” or “limitations”) which together make up the claim. A claim must be reviewed in its entirety or, as is sometimes said, “as a whole.” Every patent must have at least one claim. Claims appear at the very end of the patent and, if there is more than one, the claims are numbered. According to the Supreme Court, the construction of a patent, “including terms of art within its claims,” is exclusively within the province of the court.

18. A more detailed discussion of claims is set forth in Exhibit C.

The Examination of Patent Applications in the PTO

19. The PTO is an agency within the United States Department of Commerce. It is physically located in Alexandria, Virginia. It is fully funded by fees paid by its users, including applicants for patents and owners of issued patents. The principal responsibility of the PTO with respect to its patent operation is to examine patent applications to determine whether they should issue as patents. The governing authorities, in decreasing order of importance, are the statutory provisions set forth in Title 35 of the United States Code (35 USC), court decisions, the codified Patent Rules of Practice set forth in Title 37 of the Code of Federal Regulations (37 CFR), and the Manual of Patent Examining Procedure (MPEP), which sets forth additional guidelines and instructions to examiners.

20. The PTO currently employs about 4000 patent examiners, each of whom is assigned to a particular class or specialty of technology corresponding to the individual

examiner's science or engineering degree and/or work experience, if any. Generally speaking, examiners have an undergraduate degree (a limited number having an advanced degree) in some field of science or engineering, but little or no actual experience working in the field. They are therefore normally not persons skilled in the art to which they are assigned. However, they are assumed to have some expertise in interpreting prior art references and to be familiar from their work with the level of skill in the art. The patent applications on an examiner's docket normally fall within the subclass or specialties assigned to that examiner. Some examiners are lawyers, but many are not.

21. In examining a patent application an examiner is expected first to obtain an understanding of the application and claimed invention and then search the most relevant prior art available to the examiner. The "prior art" under United States law is very extensive. It includes all patents throughout the world, all printed publications throughout the world (which may include electronic publications and websites), and all prior public use activity, on sale activity, public knowledge by others, and inventions by others in the United States.

22. Prior art in the form of trade literature, sales brochures, some scientific publications, and some foreign patents are generally not available to examiners. The same is true with respect to prior public knowledge, prior public uses, prior sales and offers for sale of products in commerce, and prior inventions of others. Examiners do not have the benefit of technical experts or other workers in the field with whom to consult. Nor do examiners have the benefit of laboratories with which to carry out experiments to verify the accuracy and completeness of statements made in a patent specification, in affidavits and declarations, and in arguments made during prosecution of the application.

23. The examination of patent applications is *ex parte* in nature; the public does not participate. Historically, patent applications and their examinations (subject to a few limited exceptions) were required by statute to be kept in confidence. (Legislation enacted in 1999 now provides for the automatic publication of many applications after eighteen months.) Generally speaking, each examiner has many (typically over a hundred) patent applications on his or her docket at any given time, and therefore has a limited time to devote to each patent application.

24. The examination of an application in the PTO usually entails a multi-stage process of submission, rejection by the examiner accompanied by commentary explaining the reasons for the rejection, response by the applicant, etc. An applicant's response often entails amending claims to narrow their scope in an attempt to avoid prior art. Applicants also frequently present arguments as to why their claims are patentable over the prior art. Evidence in the form of an affidavit or declaration is sometimes submitted by the applicant.

25. PTO regulations permit interviews between examiners and applicants, their attorneys or agents. Such interviews may be in person in an examiner's office or by telephone.

26. The exchanges between an applicant and the examiner constitute what is called "patent prosecution." Historically, the patent prosecution papers have been maintained in the PTO in a folder called a "file wrapper". In recent times an electronic copy of these papers, as well as an electronic copy of the application papers themselves, make up what is called an "image file wrapper" or IFW. In either case, these materials constitute the official record of a patent's history. The prosecution history may be an important instrument in determining the scope of an issued patent.

27. 37 CFR § 1.56 (1992), commonly referred to as PTO “Rule 56,” reads in part as follows:

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section...

28. Examiners expect and rely on inventors and their attorneys or agents to be truthful and to act with candor and good faith in dealing with the PTO, as required by the PTO regulations and case decisions. The duty applies to all individuals associated with the filing or prosecution of an application. These individuals have a duty to disclose information known to one or more of them to be material to patentability. Examiners expect and rely on them to comply with this duty. There are several reasons for these expectations. First, as discussed above, an examiner does not have access to all prior art. Nor does an examiner have an opportunity to verify the accuracy of representations of fact known only by the inventor. Second, an affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, may mislead an examiner into granting a patent which does not meet the legal criteria. The duty of disclosure includes a duty to tell an examiner of an erroneous material representation, when discovered, during PTO proceeding.

29. Normally material prior art is called to an examiner’s attention by filing a document known as an Information Disclosure Statement (“IDS”). However, such

information may also be called to an examiner's attention in the remarks section of a response to an Office Action or in the patent application itself.

30. Prior to March 16, 1992, Rule 56 defined material information as information as to which there is a substantial likelihood a reasonable examiner would consider the information important in deciding whether to allow the application. Since March 16, 1992, Rule 56 has provided that information is material when it is not cumulative to information already of record and (1) establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or (2) refutes, or is inconsistent with, a position the applicant takes in either opposing an argument of unpatentability or asserting an argument of patentability.

31. The MPEP is an official publication of the PTO that is intended to provide patent examiners, applicants, attorneys, agents, and representatives of applicants with a reference work on the practices and procedures relative to the prosecution of patent applications before the PTO. Section 2004, entitled "Aids to Compliance With Duty of Disclosure" sets forth suggestions for complying with the duty of disclosure. Among things to be considered are: "the origin of the invention and its point of departure from what was previously known and in the prior art;" "possible public uses and sales;" and "prior publication, knowledge, patents, foreign patents, etc." Section 2004 also emphasizes that "[c]are should be taken to see that prior art or other information cited in a specification or an information disclosure statement is properly described and that the information is not incorrectly or incompletely characterized." It is further pointed out that "[w]hen in doubt, it is desirable and safest to submit information," since "[e]ven though the attorney, agent, or applicant doesn't consider it necessarily material, someone

else may see it differently and embarrassing questions can be avoided.” In this regard, the Manual points out that one district court has stated: “In short, the question of relevancy in close cases, should be left to the examiner and not the applicant.” The Manual also notes that “[i]t may be desirable to submit information about prior uses and sales even if it appears that they may have been experimental, not involve the specifically claimed invention, or not encompass a completed invention.” Thus the MPEP strongly suggests erring on the side of disclosure. (The quoted passages from the MPEP appeared in the Manual throughout the pendency of the application leading to the ‘446 patent.)

32. The duty of inventors and their attorneys or agents to disclose material information is a continuing duty that runs throughout the entire pendency of a patent application.

33. In reviewing an application, an examiner is expected to determine whether the specification contains a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which the invention pertains to make and use the invention without undue experimentation. To the extent possible, he or she also reviews the application to see whether the best mode contemplated by the inventor of carrying out her invention is disclosed. These requirements are sometimes called (1) the “written description” requirement, (2) the “enablement” requirement, and (3) the “best mode” requirement.

34. An examiner is expected to understand that the test for the written description requirement is whether the disclosure of the application reasonably conveys to one skilled in the art that the inventor had possession of the claimed subject matter at the time the application was filed and that the test for the enablement requirement is whether the

specification, viewed from the perspective of a person skilled in the art, teaches such a person how to make and use the claimed subject matter without having to resort to undue experimentation.

35. In determining compliance with the “written description” and “enablement” requirements, an examiner is expected to understand that a broad or generic term found in a specification does not necessarily cover any and all technology that might otherwise seem to be embraced by the term. One must also consider the context in which the term is used. For example, if the specification indicates that the technology designated by the term must possess certain characteristics or properties, then things that do not possess those characteristics or properties should not be deemed to be “described” or “enabled” simply because the term is used.

36. An examiner is expected to determine whether a patent specification concludes with one or more claims which particularly point out and distinctly claim the subject matter that the applicant regards as his invention. This requirement is sometimes called the requirement for “definiteness”. In doing so, an examiner is expected to consider that a claim should set out and circumscribe a particular area with a reasonable degree of precision and particularity. The definiteness of claim language must be analyzed in light of the teachings of the prior art and of the disclosure in the specification as it would be interpreted by a person possessing the ordinary level of skill in the pertinent art. An examiner would be expected to understand that the principal sources for construing claims is the language of the claim and the disclosures of the specification, and that transitional terms such as “comprising”, “consisting of”, and “consisting essentially of” should be construed according to their well-established meanings in the law.

37. An examiner is expected to determine whether a claim is directed to subject matter that is new relative to the prior art. In doing so, an examiner is expected to recognize that a claim is not directed to new subject matter if a single item of prior art anticipates, *i.e.*, identically discloses each element of the claimed invention in the claimed relationship.

38. An examiner is expected to determine whether a claim is directed to subject matter that, although novel, satisfies the requirement for nonobviousness. In doing so, an examiner is expected to consider the level of skill in the art, the scope and content of the prior art, and the differences between the prior art and the claimed invention. Against this background, the examiner is expected to determine whether the subject matter of the claim as a whole would have been nonobvious to a person having ordinary skill in the art at the time the invention was made. Any “secondary” consideration evidence submitted by an applicant must be taken into account. Such evidence is sometimes presented in a declaration or affidavit. Examples of secondary considerations indicative of the nonobviousness of a claimed invention are long felt need, prior attempts and failures, acceptance by others, including copying, simultaneous developments, and commercial success. The results achieved by an invention may also constitute evidence of nonobviousness if they are unexpected, *i.e.*, not taught or suggested by the prior art.

39. An examiner is expected to understand that prior art documents are deemed to be addressed to persons of ordinary skill in the pertinent art, and that for purposes of evaluating nonobviousness issues, a prior art document should be considered from the standpoint of what it teaches or suggests to one having the knowledge of a person of ordinary skill in the art. Obviousness is to be determined as of the time the invention was made or one year prior to the filing date. An examiner is also expected to understand that

a conclusion of obviousness cannot properly be made unless the state of the art is such as to provide a motivation or reason for the person of ordinary skill to combine the teachings of the prior art.

40. The practice of combining the teachings of two or more prior art “references” can be illustrated as follows: Suppose an examiner is reviewing a patent application claiming a chair that has rollers. The examiner finds a prior patent or printed publication that discloses a chair without rollers. The examiner finds another prior patent or printed publication that discloses a piano that has rollers and explains that the rollers make the piano easier to move. The examiner rejects the claim before her as not being in compliance with the requirement for nonobviousness. In doing so, the examiner reasons that it would have been obvious to a person of ordinary skill in the furniture art, in view of the combined teachings of the two references (which the hypothetical person of ordinary skill in the art is presumed to know), to modify the prior art chair by making it with rollers, and that when so modified one obtains the subject matter being claimed. The examiner also explains that the motivation or reason for modifying the prior art chair in this manner is provided by the knowledge of the person having ordinary skill that rollers make the piano easier to move. Indeed, in this simple example the examiner alternatively might reason that one skilled in the art would be motivated to modify the prior art chair by making it with rollers, because rollers are well known generally to workers in the art (even to lay people) to make things such as furniture easier to move; however, the piano reference reinforces this contention considerably.

41. Since the examination of a United States patent application is an *ex parte* proceeding, an examiner need only establish a *prima facie* case of obviousness in order to

shift the burden of going forward to the applicant. In his response, an applicant may challenge whether a *prima facie* case has been established or, alternatively, attempt to overcome the *prima facie* case by submitting evidence in affidavit or declaration form which purports to demonstrate nonobviousness of the claimed subject matter. This evidence may include test data or experimental results obtained from a comparison of the claimed subject matter with the prior art. All relevant data must be disclosed. It is not proper to submit to the PTO only favorable results and withhold unfavorable results because to do so would be misleading.

42. An examiner is expected to understand that under certain circumstances an applicant is entitled to bring forward evidence (in the form of declarations or affidavits) establishing a date of invention prior to the application's filing date, and thereby overcome (*i.e.*, antedate) one or more prior art references. This may be done by proving a conception and an actual reduction to practice of the claimed invention prior to the effective date of the reference. The determination of the date of an invention is claim specific. Conception is defined as the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice. Normally the only corroboration required is of the formation of the idea or concept by the inventor. The invention is regarded to have been actually reduced to practice when the concept has been embodied in some physical form that contains every limitation of a claim and that is demonstrated to be a workable embodiment. In some instances, laboratory testing of a physical embodiment may be sufficient to demonstrate its workability for its intended purpose or use. In other instances, testing under commercial or actual conditions of intended use may be required to establish actual reduction to practice. Normally

corroboration must be provided in the form of direct or circumstantial evidence that the embodiment of the invention was constructed and was demonstrated to work successfully. This can include testimony of a co-employee with first hand knowledge of the work done. Conception determines “who” made the invention and controls the question of inventorship, whereas reduction to practice determines “when” the invention was made.

TESTIMONY SPECIFIC TO THIS CASE

Preliminary Remarks

43. I understand that the claims of the ‘446 patent being asserted in this litigation are independent claim 1 and dependent claims 2, 8 and 12 (“the asserted claims”). I also understand that the parties disagree as to the meaning of the term “PE” that appears, directly or indirectly, in all of the asserted claims. More specifically, I understand that the parties disagree as to whether ultra high molecular weight polyethylene (“UHMWPE”) is within the scope of the claims. Finally, I understand that the Court has yet to resolve this dispute.

Prosecution History

44. I expect to explain the prosecution history of the ‘446 patent. More specifically, I expect to testify regarding the events that occurred during the prosecution by identifying and discussing in varying degrees certain of the papers appearing in the file history. More specifically yet, I expect to explain what prior art and other information was and was not considered by the examiner, what objections, rejections and statements were made by the examiner, and what responses and amendments were made by the applicants. This testimony would be essentially descriptive and explanatory in nature, and include at least some of the following points.

45. On February 19, 1992, an application for patent entitled “Sterilized Heterogeneous Braids” was filed in the PTO in the names of Alastair W. Hunter, Dennis D. Jamiolkowski, Arthur Taylor, Jr. and Mark Steckel. It was assigned application No. 07/838,511. It contained three sheets of drawings, which included three Figures. It contained twenty-four claims, claims 1-20 being directed to a “heterogeneous braid” and claims 21-24 being directed to a “surgical suture.”

46. The Declaration accompanying the application and which was signed by the four named inventors contains the following statements:

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

47. On the same day, an Information Disclosure Statement was filed which identified eleven references, five of which were said by Mr. Goodwin to have been discussed in the Background of the Invention. Mr. Goodwin also stated that the additional six references “may be relevant” to the examination of the application. In doing so, he had this to say with respect to one of them:

U.K. Patent Application GB 2 218 312A [Burgess], discloses a fishing line of braided construction, some braid filaments being composed of polythene and other filaments composed of polyester and/or nylon.

48. On July 8, 1992, the examiner required restriction between “claims 1-20, drawn to a heterogeneous braid” and “claims 21-24, drawn to a surgical suture,” saying that the two groups of claims “are related as mutually exclusive species in intermediate-final product relationship.” The examiner explained that distinctness “is proven for

claims in this relationship if the intermediate product is useful to make other than the final product...and the species are patentably distinct....” Further, the examiner explained that “in the instant case, the intermediate product is deemed to be useful as a fishing line and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants.” In a telephone conversation, Mr. Goodwin made a provisional election of claims 21-24, *i.e.*, the claims drawn to a surgical suture.

49. In the same Office Action, the examiner rejected claims 21-24 under 35 U.S.C. 103 as being unpatentable over Burgess. On August 6, 1992, Mr. Goodwin mailed a response to the PTO in which he sought to refute the examiner’s rejection and underlying reasoning.

50. In the next Office Action, dated November 2, 1992, the examiner dropped his rejection based on Burgess. In responding to the Office Action, on December 2, 1992, Mr. Goodwin stated that:

Applicants acknowledge with gratitude the withdrawal of the rejection of claims 21-24 under 35 USC §103 as being unpatentable over Burgess, expressed in the previous Office Action dated July 8, 1992. (Paper No. 3). It is presumed that Applicants’ response to this rejection in their Amendment dated August 6, 1992, spelling out the distinctions between Burgess and the claimed invention, clearly convinced the Examiner that the claimed surgical suture is patentable over this art.

51. On March 18, 1993, the examiner continued to reject all claims, but not on Burgess. On August 4, 1993, a new attorney, Mr. Woodrow, mailed to the PTO an Amendment in which application claim 21 was amended. Amended claim 21 became claim 1 of the ‘446 patent. On the same day, Mr. Woodrow mailed an IDS. The IDS called the examiner’s attention to five U.S. patents and one British patent.

52. The application was allowed on November 18, 1993, and it issued on May 24, 1994 as the '446 patent.

Specific Opinions and Conclusions

53. Based upon my study of this case to date, I have formed the following opinions and reached the following conclusions.

54. If the term "PE" in the asserted claims of the '446 patent is construed by the Court to include ultra high molecular weight polyethylene ("UHMWPE"), then they are invalid for failing to satisfy the written description and enablement requirements of the first paragraph of 35 U.S.C. 112. (Since dependent claims 2, 8 and 12 do not limit claim 1 with respect to the term PE, they are subject to the same claim construction and are invalid under this claim construction for the same reasons that apply to claim 1.) The bases for my opinion include the principles set forth in paragraphs 33-35, *supra*, and the expected testimony of Dr. Mukherjee as set forth in his Report.

55. If the term "PE" in the asserted claims of the '446 patent is construed by the Court to include UHMWPE, then they are invalid for failing to satisfy the novelty requirement because they are anticipated by Chesterfield *et al.* I understand that the plaintiff contends that the invention of the '446 patent was reduced to practice "at least as early as February 2, 1989" (Supp. Resp. to Int. No. 6) *i.e.*, three years before the February 3, 1992 filing date of Chesterfield *et al.* I disagree. I find no evidence that a "surgical suture," as required by each asserted claim, was constructed. I find no evidence that "a sterilized, braided construction," as required by each asserted claim, was built before the effective date of the reference. Furthermore, the braided structures that were built appear to have experienced substantial problems with core popping and braid

looseness. And in a handwritten note dated February 9, 1990, Dr. Schwartz specifically referred to “technical problems of mixing 2 materials with dissimilar stress/strain properties.” (Bates No. DMI095020.) This notation is entirely consistent with the fact that I have seen no evidence indicating that these problems had been solved prior to February 2, 1989. Nor have I seen evidence that they had been solved prior to the February 19, 1992 filing date of the ‘446 patent. Under the circumstances, Chesterfield *et al.* is a prior art reference under 35 U.S.C. 102(e). The bases for my opinion include the principles set forth in paragraphs 37 and 42, *supra*, and the expected testimony of Dr. Mukherjee as set forth in his Report both with respect to the disclosure of Chesterfield *et al.* and the lack of proof of a reduction to practice.

56. If the term “PE” in the asserted claims of the ‘446 patent is construed by the Court to include UMHWPPE, then they are invalid for failing to satisfy the nonobviousness requirement of 35 U.S.C. 103 in view of the following prior art references: Burgess, the Dyneema brochure, the Cohan *et al.* article, and Harpell *et al.* ‘286 and ‘392. The bases for my opinion include the principles set forth in paragraphs 38-40, *supra*, and the expected testimony of Dr. Mukherjee as set forth in his Report.

57. Regardless of whether the Court construes the term PE to include UHMWPE, I would expect to testify that the asserted claims are invalid for failing to satisfy the nonobviousness requirement of 35 U.S.C. 103 in view of Silvestrini *et al.* and the ‘802 patent to Mares *et al.* The bases for my opinion include the principles set forth in paragraphs 38-40, *supra*, and the expected testimony of Dr. Mukherjee as set forth in his Report.

58. If the term “PE” in the asserted claims of the ‘446 patent is construed by the Court to include UMHWPPE, then I would expect to testify that Dr. Steckel, and Mr. Hunter, and/or Mr. Goodwin may have violated their duty to disclose material information to the PTO, as required by Rule 56. The bases for my opinion include the principles set forth in paragraphs 27-32, *supra*, the deposition testimony of Dr. Steckel, the deposition testimony of Mr. Goodwin, the arguments by Mr. Goodwin in his response mailed on August 6, 1992, as set forth in paragraph 49, *supra*, and the January 23, 2006 privileged document list. A more specific discussion is set forth below.

59. According to Dr. Steckel, he and at least co-inventor Hunter conceived of a braid construction made up of two dissimilar materials for use as a surgical suture, and that one such construction that they contemplated was the combination of UHMWPE (specifically, Spectra or Dyneema) and PET. Mr. Goodwin and Dr. Steckel jointly prepared the ‘511 application that ultimately led to the ‘446 patent. I understand that Dr. Steckel was Mr. Goodwin’s principal contact with respect to the preparation and prosecution of the ‘446 patent and that materials during prosecution were sent to Mr. Hunter.

60. As discussed in paragraph 49, *supra*, the examiner rejected claims 21-24 (all claims then being examined) as being unpatentable over Burgess. Burgess contains the following disclosure:

According to the present invention there is provided a fishing line of braided construction, some braid filaments being of high tensile polythene thread and other filaments being of polyester and/or nylon.

The high tensile polythene gives the line minimal stretchability and will preferably be a high molecular weight polythene, melted in a solvent and drawn at high speed into extremely fine strands. This produces almost

perfect alignment of all the molecules in long chains. A suitable product is that sold under the Registered Trade Mark DYNEEMA.

61. In responding to this rejection, Mr. Goodwin represented to the examiner that if a medical designer were to actually build a surgical suture using the braided combination of UHMWPE and polyester, then “he would inevitably design an unacceptable suture.” In his response, Mr. Goodwin also represented to the examiner that the braided combination disclosed in Burgess would have “poor knot strength properties.”

62. Dr. Steckel’s testimony regarding the use of UHMWPE in a braided suture is the opposite of what Mr. Goodwin represented to the examiner. Dr. Steckel also testified that he and Mr. Hunter discussed braiding UHMWPE and polyester prior to the filing date of the ‘511 application and that they believed it would lead to an acceptable suture. Further, Dr. Steckel testified that at the time he considered such a combination to be “a good idea” and that braiding UHMWPE and polyester together would result in “improved knot strength.”

63. In my opinion, the arguments presented to the examiner with respect to alleged distinctions between the claimed invention (assuming the claims include UHMWPE) and Burgess are inconsistent with Dr. Steckel’s testimony. It is also my opinion that, accepting Dr. Steckel’s testimony as true, the representations made to the examiner are misrepresentations in highly material respects, because they were made for the purpose of overcoming a prior art rejection in order to obtain the allowance of claims for issuance in a patent.

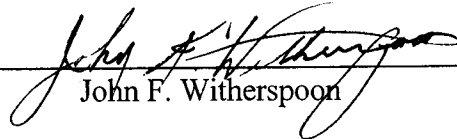
EXHIBITS

64. I have not at this time prepared any exhibits which I expect to use as summary of or support for my opinions. However, I would expect to use during my testimony at trial at least some of the documents listed above under "Information Considered". I may also use demonstrative exhibits, summaries, or other exhibits that are not yet prepared, to further illustrate my testimony. I understand that such exhibits would be exchanged with opposing counsel at a time to be mutually agreed upon or required by the Court.

COMPENSATION

65. I am being compensated for my work on this case at my customary rate of \$600 per hour, plus expenses. My compensation is not based on the outcome of the litigation.

March 3, 2006



John F. Witherspoon

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Expert Report of John F. Witherspoon was served, via Fedex (Saturday delivery to Ms. Malinoski and regular delivery to Mr. Gleason), along with a courtesy copy of the text of this report (without exhibits), via email, on the following counsel for Plaintiff on the 3rd day of March 2006:

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s/Salvatore P. Tamburo

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

REBUTTAL EXPERT REPORT OF JOHN F. WITHERSPOON

I am the same John F. Witherspoon who submitted expert reports in this litigation on March 3, 2006 and March 24, 2006, which reports I incorporate herein by reference. I have reviewed the expert report of Dr. Matthew Hermes and I submit this report in response to aspects of Dr. Hermes' report that relate to patent practices and procedures, including his reply to certain opinions set forth in my March 3 report. I have also reviewed the Rebuttal Expert Report of Dr. Debi Prasad Mukherjee, as well as the transcript of the deposition of Donald Grafton given on March 14, 2006.

I.

1. I do not fully understand the significance of the attempt to distinguish between "a person of ordinary skill in the art" and "a person of skill in the art" in paragraph 31 of the Hermes report, because this seems to suggest that the level of skill of the persons referenced in sections 103 and 112 of the statute is not the same. I am not aware of any authority in support of this position.

2. Much of the discussion in the sections of the Hermes report dealing with a motivation to combine various prior art references is based on a number of false premises. (See, especially paragraphs 48-60, 110-117, 125-129 and 139-142.) For example, the report suggests that the motivation must be found in the references themselves. That is not a requirement. The teaching, motivation, or suggestion to combine relevant prior art disclosures does not have to be found explicitly in the prior art. Rather, it may be provided by a consideration of the prior art as a whole. The test is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art. In this regard, the problem to be examined is not the specific problem solved by the invention, but the general problem that confronted the inventor before the invention was made, and to the extent paragraphs 21 and 22 of the Hermes report indicate otherwise, I disagree.

II.

3. In paragraphs 168-184, Dr. Hermes attempts to explain that the claimed invention was reduced to practice at least as early as February 1989. Evidence of a reduction to practice must reflect every limitation recited in the claims. I fail to find any discussion in Dr. Hermes's report of evidence demonstrating the actual making and evaluation of a sterilized surgical suture by the inventors. Further, a three year wait before filing a patent application after an alleged reduction to practice is itself some evidence that a reduction to practice may not have occurred as early as alleged.

4. The most that Dr. Hermes has identified by way of an alleged reduction to practice is a braided structure made of PTFE and PET. Even assuming that such a braid

constitutes a reduction to practice for that combination, it fails to antedate Chesterfield as a prior art reference unless it is established that that work would be understood by a person of ordinary skill in the art to have generic applicability to the claimed braided structures of sufficient scope as to embrace a braid made of UHMWPE and PET or nylon. I find no such demonstration in the Hermes report.

III.

5. In paragraphs 185-194, Dr. Hermes attempts to explain that certain statements to the examiner by the applicants' attorney, Mr. Goodwin, while prosecuting the '446 patent were not inconsistent with Dr. Steckel's testimony. I disagree with Dr. Hermes. Nothing in his report causes me to change my opinion.

6. In his deposition, Dr. Steckel gave the following testimony (page 188, line 13 to page 192, line 9):

Q. And when you say, "Spectra," if I were to substitute Dyneema, Spectra or Dyneema –

A. Yes. Yeah.

Q. -- that would be a fair thing?

A. Yes.

Q. Did you have an idea of which yarn you—to braid Dyneema with?

A. Which yarn would we have braided it with?

Q. Yes, sir. Did you have that idea?

MR. BONELLA: Objection. Asked and answered.

A. Generically, one which would improve the knot strength of Dyneema.

Q. Would that include PET?

A. It would include, essentially, all of the current—all of Ethicon's non-absorbable multifilaments at the time, which would include PET, nylon, silk—that's it.

Q. So, if I understand your testimony—

A. Yes.

Q. --you had, at least in your mind—

A. Yes.

Q. --the idea of braiding together Dyneema and PET.

A. It was one of the combinations, yes.

Q. And did you have a view—and when did you have this idea?

- A. This—this would date back to the early conversation with Al Hunter in terms of what benefits could we derive from forming composites of dissimilar fibers.
- Q. Did you have—in formulating this idea, did you have any sort of belief that if you put Dyneema together with PET, it would lead to an acceptable suture?
- A. It would lead to a suture with potentially improved properties over Ethibond.
- Q. Did you have a belief as to whether that would be an acceptable suture?
- MR. BONELLA: Objection. Asked and answered.
- A. We had a belief that it could lead to—as you’re saying—an acceptable suture. There were other issues that we didn’t know. For example, how the—how polyethylene behaved in the body. So, it was a high priority. Polyethylene, even though there was an interest, it wasn’t a—it wasn’t something that was a high priority at the time.
- Q. The thought didn’t cross your mind that, Oh, this would make an unacceptable suture to put Dyneema together with PET?
- A. My recollection was—an unacceptable suture or an acceptable?
- Q. An unacceptable suture.
- A. Well, the concern with any of the very high-strength fibers was always knot strength, and that was true whether it was Dyneema, Spectra, Kevlar, etcetera. So, the general view was, I mean, all of those—100 percent, all of those, Ethicon evaluated at one point as a suture material. They’re the world’s biggest suture material company. And all of them there was an interest in how do you improve the knot strength of them, and can you—that was—that was something we discussed.
- Q. I’m not sure I understand your answer.
- A. Go ahead.
- Q. And I’m trying to—
- A. Sure.
- Q. When you had this idea that you could blend Dyneema together with PET, were you—did you believe it would make an acceptable suture or an unacceptable suture?
- A. No. We believed—we believed that that could offer a suture with straight tensile that was better than Ethibond, and you know, could potentially solve the knot issues, and again, that was a generic view for all of the high-tenacity fibers.
- Q. You thought it was a good idea—
- A. Yes. Yes.
- Q. --rather than a bad idea?
- A. No., we viewed—we viewed that as a potential good idea.
- Q. And you didn’t think, Oh, that’s a bad idea.
- MR. BONELLA: Objection. Asked and answered.
- A. I don’t know if it was good or bad. You now, it was—

Q. You thought it was a good idea?

A. We thought we could have improved knot strength, and we could get the beneficial properties of both in a blend. That's what we thought.

Thus, according to Dr. Steckel, before filing their application in the PTO the applicants believed that a braided structure of Dyneema and PET (a polyester) could have good knot characteristics. They believed that this combination could lead to an acceptable suture.

7. During prosecution of their application, however, when faced with a rejection based on a prior art disclosure (Burgess) of a fishing line having a braided structure of a high molecular weight polyethylene, Dyneema being specifically named, with polyester and/or nylon, the applicants tried to convince the examiner that their braid was patentable over the braid of the fishing line by making the following representations (Amendment mailed August 4, 1982) (all emphases in original):

In fact, the fishing line of Burgess would have poor knot strength properties because of its braided construction, as set forth in more detail below: (Page 2)

Therefore, the property requirements for fishing line yield a braid with poor knot strength and security, and the requirements for sutures yield a braid which has by necessity excellent knot strength and security. (Page 3)

Even if he did use the teachings of the fishing line art to modify a suture, then he would inevitably design an unacceptable suture. (Pages 3-4)

The examiner's rejection on Burgess was then dropped, which the applicants acknowledged with gratitude.

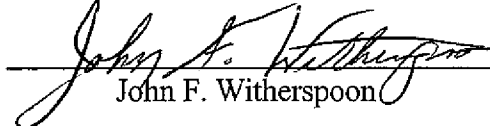
8. In my opinion, the statements made to the examiner are not consistent with Dr. Steckel's testimony. On the one hand, according to Dr. Steckel, he and Mr. Hunter believed that a braid of Dyneema and PET could provide an acceptable suture with improved knot strength characteristics; on the other hand, they told the examiner that the

Burgess braid would have poor knot strength properties. It is also my opinion that the statements made to the examiner are affirmative misrepresentations, if the applicants believed that their claims included braids of Dyneema and PET. And they are highly material misrepresentations, because they were made in an attempt to overcome a rejection based on a very close prior art reference, which attempt turned out to be successful.

9. Dr. Hermes has four responses to my opinion. First, he says that in my earlier report I failed to include the words “the teachings of the fishing line art” in the last of the three quotations set forth above. I do not understand his point. My earlier discussion was clearly referring to the fishing line art as disclosed in Burgess, namely a fishing line of a braid having Dyneema filaments and filaments of polyester and/or nylon. In any event, I have now included the words in the quotation above, and my opinion remains the same. Second, Dr. Hermes says he is not clear what statements by Dr. Steckel I have in mind. The statements are easily found in the transcript and they are set forth above. Third, Dr. Hermes says that Dr. Steckel’s testimony is not inconsistent with the attorney’s statements. As already indicated, I very much disagree. Dr. Steckel testified that he and Mr. Hunter believed that the combination of Dyneema and a polyester could lead to an acceptable suture with improved knot strength. Mr. Goodwin represented the opposite in the applicants’ successful attempt to overcome prior art. A braid that could lead to an acceptable suture with improved knot strength does not become otherwise by calling it a fishing line. Fourth, Dr. Hermes says that nothing was withheld from the examiner because the application of the ‘446 patent “discloses ultra high molecular weight polyethylene, UHMWPE.” Dr. Mukherjee does not agree. In any

event, I fail to find any mention of the terms “Dyneema,” “Spectra,” “ultra high molecular weight polyethylene,” or “UHMWPE” anywhere in the ‘446 patent. (Nor, incidentally, do I find any of this terminology anywhere in Dr. Steckel’s notebooks that I reviewed.) In my opinion, no reasonable examiner would have dropped a rejection based on Burgess if she believed that the applicants’ claims included a braid of Dyneema and PET, based on the arguments made by the applicants. Many of the attorney’s arguments would have been irrelevant, since the claims do not recite such properties as elongation and knot strength and security, upon which to distinguish the disclosure of Burgess. In my opinion, the examiner here must have believed that the claims did not include braids of Dyneema and PET.

April 13, 2006


John F. Witherspoon

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Rebuttal Expert Report of John F. Witherspoon was served, via Fedex, on the following counsel for Plaintiff on the 13th day of April 2006:

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_____/s/Salvatore P. Tamburo

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC., a Massachusetts)
Corporation,)
Plaintiff,) Civil Action
v.) No. 04-12457 PBS
ARTHREX, INC., a Delaware)
Corporation,)
PEARSALLS LTD., a Private Limited)
Company of the United Kingdom,)
Defendants.)

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VIDEO DEPOSITION OF JOHN WITHERSPOON

Washington, D.C.

Tuesday, June 20, 2006

The videotaped deposition of JOHN WITHERSPOON was
convened on Tuesday, June 20, 2006, commencing at
9:03 a.m., at the offices of Dickstein Shapiro Morin
& Oshinsky LLP, 2101 L Street, Northwest,
Washington, D.C., before Cynthia R. Simmons Ott,
Registered Merit Reporter, Certified Realtime
Reporter, and Notary Public.

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|---|--|
| <p style="text-align: right;">138</p> <p>1 respect to the materiality of a representation
 2 made by Attorney Goodwin to the Patent Office
 3 during prosecution of the Hunter patent?
 4 A. Well, I formed an opinion that the
 5 representations made by counsel to the examiner
 6 with respect to an effort which was successful
 7 in getting rid of a rejection based on Burgess,
 8 and statements made by Dr. Steckel in his
 9 deposition, are not consistent.
 10 So you could look at it either of two
 11 ways. That the statements by the attorney
 12 should not have been made, that those are
 13 material because they're inconsistent with the
 14 facts as testified to by Dr. Steckel, or that
 15 if they were made, there was material
 16 information withheld, namely the information
 17 that Dr. Steckel testified to. Either way,
 18 when you look at the situation from the
 19 standpoint of the examiner examining the case,
 20 the examiner didn't have the full story.
 21 Q. Do you plan to testify that material
 22 information was withheld from the examiner?
 23 A. Well, you know, obviously, I don't
 24 know what questions I'll be asked. But if
 25 asked, I would so testify.</p> | <p style="text-align: right;">140</p> <p>1 Q. And if PE in the patent is construed
 2 by the Court to encompass ultra high molecular
 3 weight polyethylene, then it's the case, is it
 4 not, that the patent discloses that a braid, a
 5 successful -- a suture can be successfully made
 6 by a, out of a combination of ultra high
 7 molecular weight polyethylene and PET?
 8 A. Would you repeat that, please?
 9 THE REPORTER: "Question: And if PE
 10 in the patent is construed by the Court to
 11 encompass ultra high molecular weight
 12 polyethylene, then it's the case, is it not,
 13 that the patent discloses that a braid, a
 14 successful -- a suture can be successfully made
 15 by a, out of a combination of ultra high
 16 molecular weight polyethylene and PET?"
 17 MR. SABER: Objection, vague and
 18 overbroad.
 19 THE WITNESS: Well, I'm not sure we
 20 mentioned this, but my prior testimony about
 21 the withholding of material information is
 22 conditioned on the Court construing the claim
 23 as to cover ultra high molecular weight
 24 polyethylene.
 25 BY MS. ELDERKIN:</p> |
| <p style="text-align: right;">139</p> <p>1 Q. And what material information would
 2 you testify was withheld from the examiner?
 3 MR. SABER: Objection, asked and
 4 answered.
 5 THE WITNESS: That Dr. Steckel and --
 6 at least Dr. Steckel, and perhaps Mr. Hunter as
 7 well, believed back in 1988 or '89 that a braid
 8 made of Spectra, an ultra high molecular weight
 9 polyethylene and polyethylene terephthalate,
 10 PET, could provide a successful suture, could
 11 provide a braid which could be converted into a
 12 successful suture.
 13 BY MS. ELDERKIN:
 14 Q. And it's your opinion that that was a
 15 material bit of information for the examiner?
 16 A. Yes, because contrary information was
 17 being told to the examiner. Absent the
 18 contrary information, then I would not consider
 19 this information to be material. But it's
 20 material because it is inconsistent with what
 21 had been told to the examiner.
 22 Q. Okay. And which of the tests for
 23 materiality are you applying in arriving at
 24 that conclusion?
 25 A. Either one.</p> | <p style="text-align: right;">141</p> <p>1 Q. So if the Court considers that PE
 2 includes ultra high molecular weight
 3 polyethylene, then one skilled in the art
 4 reading the Hunter patent application would
 5 understand that PE, when it's referenced, would
 6 include ultra high molecular weight
 7 polyethylene, right?
 8 MR. SABER: Objection, vague.
 9 THE WITNESS: Well, I think several
 10 issues are being mixed. If I understand your
 11 question correctly, my response is that a court
 12 can construe a claim in such a way that it's
 13 invalid. It doesn't follow that if this court
 14 were to construe PE in the claim to include
 15 ultra high molecular weight PE, that it's a
 16 valid claim.
 17 Those are other issues to be decided
 18 at another time and place. So what the
 19 significance of that insofar as what the
 20 disclosure is, and so on, have not been fully
 21 decided, simply by virtue of the claim
 22 construction.
 23 BY MS. ELDERKIN:
 24 Q. Right. But if the Court finds that
 25 one skilled in the art would read the term PE</p> |

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| <p style="text-align: right;">182</p> <p>1 analysis?</p> <p>2 A. I'd have to see his report.</p> <p>3 Q. Did you consider long felt need in</p> <p>4 adopting his obviousness conclusion?</p> <p>5 A. I considered it as a factor to take</p> <p>6 into account if I was aware of it, but I did</p> <p>7 not focus on it, because I wasn't aware of any</p> <p>8 such secondary considerations.</p> <p>9 Q. Did you consider or did Dr. Mukherjee</p> <p>10 consider commercial success in arriving at his</p> <p>11 obviousness conclusion?</p> <p>12 A. I need to see his report.</p> <p>13 Q. Did you consider commercial success?</p> <p>14 A. Again, I did not make a study of it,</p> <p>15 an investigation of it.</p> <p>16 Q. Did you consider it at all?</p> <p>17 A. Well, I considered it to the extent</p> <p>18 that typically in a litigation, if infringement</p> <p>19 is found, there's typically some commercial</p> <p>20 success. But that begs the question as to</p> <p>21 whether the commercial success of the defendant</p> <p>22 here is evidence of nonobviousness of the</p> <p>23 claimed subject matter.</p> <p>24 Q. Did you consider whether the</p> <p>25 commercial success here was the result of the</p> | <p style="text-align: right;">184</p> <p>1 A. Unexpected. Well, that's -- what I</p> <p>2 said seems to me is equitable in part for all</p> <p>3 these factors. The short answer is, no, I did</p> <p>4 not look at each of the -- of the secondary</p> <p>5 considerations, and undertake an evaluation as</p> <p>6 to whether they're entitled to too much weight.</p> <p>7 Q. In paragraph 58 of your first report,</p> <p>8 you begin a discussion that proceeds for</p> <p>9 several paragraphs about whether Dr. Steckel,</p> <p>10 Mr. Hunter and/or Mr. Goodwin may have violated</p> <p>11 their duty to disclose material information to</p> <p>12 the Patent Office.</p> <p>13 And I note that in that first sentence</p> <p>14 in paragraph 58, you say that "you expect to</p> <p>15 testify that these gentlemen may have violated</p> <p>16 their duty to disclose material information to</p> <p>17 the PTO." And I note the language may have</p> <p>18 violated. Do you intend to testify that they</p> <p>19 did violate their duty to disclose material, or</p> <p>20 that they may have violated their duty to</p> <p>21 disclose material information?</p> <p>22 A. Well, I don't know quite how to answer</p> <p>23 that, other than that it depends upon how the</p> <p>24 evidence at trial comes to -- comes in. And I</p> <p>25 say that because there's some additional</p> |
| <p style="text-align: right;">183</p> <p>1 claimed subject matter?</p> <p>2 A. No.</p> <p>3 Q. Do you know, did Dr. Mukherjee</p> <p>4 consider whether results achieved by the</p> <p>5 invention were unexpected?</p> <p>6 A. I don't know without looking at his</p> <p>7 report.</p> <p>8 Q. In adopting his obviousness</p> <p>9 conclusion, did you consider whether results</p> <p>10 achieved by the invention were unexpected?</p> <p>11 A. Well, with respect to many of these</p> <p>12 factors, it's my understanding that the</p> <p>13 plaintiff is not commercializing a product</p> <p>14 under the patent, but that the plaintiff</p> <p>15 contends that the defendant is. And the</p> <p>16 defendant contends they're not. So I don't</p> <p>17 know how I would quite get a handle on -- I</p> <p>18 mean, if you accept defendant's contention that</p> <p>19 they're not infringing, then there's no</p> <p>20 evidence of commercial success.</p> <p>21 Q. Okay. My question wasn't about</p> <p>22 commercial success, it was whether in adopting</p> <p>23 Dr. Mukherjee's conclusions about obviousness,</p> <p>24 you considered whether results achieved by the</p> <p>25 invention were unexpected?</p> | <p style="text-align: right;">185</p> <p>1 information that I think needs to be found, for</p> <p>2 which I don't have access now, that would bear</p> <p>3 on whether there was a violation or not.</p> <p>4 And that turns on answers to the</p> <p>5 question of who knew what when. At this point</p> <p>6 in time, there's some circumstantial evidence</p> <p>7 that suggests that Mr. Steckel was aware of</p> <p>8 what the patent examiner had been told, but I</p> <p>9 can't point to a particular document or a piece</p> <p>10 of testimony that clearly establishes that.</p> <p>11 That's the reason for the use of the word may.</p> <p>12 In other words, there's a lot of</p> <p>13 information that indicates to me that there may</p> <p>14 have been a violation here, and this isn't just</p> <p>15 pulled out of thin air. But at this point in</p> <p>16 time, I could not specifically say what</p> <p>17 Dr. Steckel knew when, or what Mr. Goodwin knew</p> <p>18 when, or Mr. Hunter knew when. But there's</p> <p>19 evidence from which one could infer that they</p> <p>20 knew.</p> <p>21 Q. And without evidence, without</p> <p>22 knowledge of what they knew, you cannot</p> <p>23 conclude that any of those gentlemen violated</p> <p>24 their duty of disclosure?</p> <p>25 MR. SABER: Objection, misstates the</p> |

47 (Pages 182 to 185)

| | |
|---|--|
| <p style="text-align: right;">186</p> <p>1 testimony.</p> <p>2 THE WITNESS: Could you read that</p> <p>3 back, please?</p> <p>4 BY MS. ELDERKIN:</p> <p>5 Q. And without knowledge of what those</p> <p>6 gentlemen knew, and when they knew it, you</p> <p>7 cannot conclude that any of them violated their</p> <p>8 duty of disclosure?</p> <p>9 MR. SABER: Same objection, misstates</p> <p>10 the testimony, inconsistent with his testimony.</p> <p>11 THE WITNESS: Well, no, I stand by the</p> <p>12 statement that I've made here, that they may</p> <p>13 have violated their duty. And I have referred</p> <p>14 to the deposition testimony of Dr. Steckel and</p> <p>15 Mr. Goodwin. But I would be -- I would not be</p> <p>16 inclined, at this point, to say that they, in</p> <p>17 fact, did violate it, knowing only what I know</p> <p>18 now.</p> <p>19 But I could say that it could well be</p> <p>20 a very -- there's a very good chance that they</p> <p>21 did, one or the other. And I'm thinking in</p> <p>22 particular -- well, any of the three. Goodwin,</p> <p>23 as I recall, said that Dr. Steckel was the</p> <p>24 point man or the person he interacted with,</p> <p>25 particularly with respect to preparing the</p> | <p style="text-align: right;">188</p> <p>1 doesn't add up.</p> <p>2 And if -- and then Goodwin goes off,</p> <p>3 he either wasn't -- it seems to me he either</p> <p>4 wasn't told that we're talking about ultra high</p> <p>5 molecular weight polyethylene here when he was</p> <p>6 writing up this patent application, or he was</p> <p>7 told and deliberately misled the examiner when</p> <p>8 it came to talking about Burgess. I don't see</p> <p>9 how both of those can be -- can be reconciled.</p> <p>10 Q. You considered the Burgess disclosure,</p> <p>11 right, you refer to it in paragraph 60 of your</p> <p>12 report?</p> <p>13 A. Yes.</p> <p>14 Q. Let me give you a copy of that. And</p> <p>15 again, sorry, we just have the one copy here.</p> <p>16 Let's put an exhibit sticker on there. We'll</p> <p>17 mark as DePuy Mitek Exhibit 379, a copy of UK</p> <p>18 patent application 2,218,312.</p> <p>19 MR. SABER: It's 379.</p> <p>20 MS. ELDERKIN: 379, yes.</p> <p>21 (DePuy Mitek Exhibit Number 379 was</p> <p>22 marked for identification.)</p> <p>23 BY MS. ELDERKIN:</p> <p>24 Q. So again, you refer to some</p> <p>25 disclosures in the Burgess patent in paragraph</p> |
| <p style="text-align: right;">187</p> <p>1 application and prosecuting it early on, which</p> <p>2 suggests to me that Dr. Steckel and Mr. Goodwin</p> <p>3 had a lot of information in common.</p> <p>4 And if we believe Dr. Steckel's</p> <p>5 testimony, which I'm prepared to accept, we</p> <p>6 have all this Spectra and PET activity and</p> <p>7 thought patterns and so on, that that's what</p> <p>8 they thought could produce a good suture. And</p> <p>9 this was well before the patent application was</p> <p>10 filed.</p> <p>11 And Goodwin worked with him in</p> <p>12 preparing the patent application. It seems odd</p> <p>13 to me that that kind of information would not</p> <p>14 have been communicated to Mr. Goodwin. The</p> <p>15 kinds of things he said in his deposition that</p> <p>16 he knew all about, and was talking to Hunter</p> <p>17 about. And yet you don't see boo in the patent</p> <p>18 application about Spectra or Dyneema or ultra</p> <p>19 high molecular weight polyethylene.</p> <p>20 It's another reason that suggests to</p> <p>21 me that that wasn't contemplated when this</p> <p>22 patent application was written. Just PE and</p> <p>23 now even though this is a hot number, this</p> <p>24 Spectra stuff, why wouldn't it have been</p> <p>25 mentioned in the patent application. It just</p> | <p style="text-align: right;">189</p> <p>1 60 of your report. I'm going to just ask you</p> <p>2 whether Burgess discloses the knot strength of</p> <p>3 any fishing line made according to its</p> <p>4 teachings?</p> <p>5 A. I don't recall seeing it there, and I</p> <p>6 don't recall seeing it in the claims, so I find</p> <p>7 these arguments irrelevant.</p> <p>8 Q. Did Burgess disclose --</p> <p>9 A. By these, I don't mean anything you</p> <p>10 said, but what Mr. Goodwin was arguing.</p> <p>11 Q. Right. Did Burgess -- did the Burgess</p> <p>12 disclosure include any reference to the knot</p> <p>13 security of the fishing line disclosed in the</p> <p>14 patent?</p> <p>15 A. Again, from my reading of the document</p> <p>16 as a patent lawyer, not a person skilled in the</p> <p>17 art, I don't see those words, and I don't have</p> <p>18 enough technical information to know whether</p> <p>19 they're implicit. Sometimes documents contain</p> <p>20 implicit disclosures such as the things you're</p> <p>21 talking about, which would not be apparent to</p> <p>22 me. Those words are missing, from the claim as</p> <p>23 well.</p> <p>24 Q. Does Burgess disclose the particular</p> <p>25 configuration of the braided structure</p> |

Deposition of:
Dr. Mark G. Steckel

January 26, 2006

Page 1

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS
4

**TRAVEL
TRANSCRIPT**

5 DePUY MITEK, INC.,)
6 Plaintiffs,)
7 vs.)
8 ARTHREX, INC., a Delaware)
9 corporation,)
10 Defendants.)
11

12 DEPOSITION of DR. MARK G. STECKEL,
13 called as a witness by and on behalf of the
14 Defendant, pursuant to the applicable provisions of
15 the Federal Rules of Civil Procedure, before P.
16 Jodi Ohnemus, Notary Public, Certified Shorthand
17 Reporter, Certified Realtime Reporter, and
18 Registered Merit Reporter, within and for the
19 Commonwealth of Massachusetts, at the Courtyard
20 Marriott, 423 Speen Street, Natick, Massachusetts,
21 on Thursday, 26 January, 2006, commencing at 10:44
22 a.m.
23
24
25

Deposition of:
Dr. Mark G. Steckel

January 26, 2006

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1 A. We were certainly looking at fiber. We
2 were certainly considering fibers that offer higher
3 tensile strength than -- than strictly PET.

4 **Q. And that was the aromids?**

5 MR. BONELLA: Object to form.

6 A. That was one of -- that was one example.

7 **Q. Is there anything else?**

8 MR. BONELLA: In the patent?

9 MR. SABER: Yes, sir.

10 MR. BONELLA: If you want to read the
11 patent, read the patent. Object to form.

12 A. Well, the patent describes generic classes
13 of polymers, and the high strength aspect of it has
14 more to do with how those polymers were processed.
15 So, any of those polymers that are listed, you
16 know, could be processed in a high strength form or
17 a medium-strength form or a low-strength form.

18 **Q. When you're saying, "these," which ones
19 are you talking about?**

20 A. I'm referring to the polymers listed in
21 the claims.

22 **Q. All of them?**

23 A. All of those can be processed to get a
24 range of low, medium, or relatively high strength.

25 **Q. All right. Let's look at the**

1 **Q. Right, in the first set.**

2 A. Right.

3 **Q. "-- that are mechanically blended with
4 yarns of the second set, which act to provide
5 improved strength to the heterogeneous braid."
6 Isn't that talking about the second set, providing
7 "improved strength to the heterogeneous braid"?**

8 A. Yeah, within the context of this
9 paragraph. But once again, PET, for example, could
10 be, you know, could be in a -- in a low strength or
11 medium strength or a high strength.

12 **Q. I'm talking about what's being -- what's
13 being explained in this paragraph.**

14 A. Okay.

15 **Q. Is this -- isn't it true that this
16 paragraph is explaining that the -- that the yarns
17 from the second set are there to provide improved
18 strength to the braid?**

19 MR. BONELLA: Object to form.

20 A. My read of this is that in this particular
21 embodiment, the second set would be offering
22 strength.

23 **Q. And that's the only yarns that are
24 specifically mentioned are PET, nylon, and aromids,
25 is that correct?**

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1 **specification, if we could.**

2 A. Okay.

3 **Q. Could you look at Column 4, please. Yes.
4 The paragraph that starts at Line 33.**

5 A. Yes.

6 **Q. Is that paragraph disclosing the polymers
7 which are to act as strength --**

8 MR. BONELLA: Object --

9 **Q. -- to provide improved strength to the
10 braid?**

11 MR. BONELLA: Object to form.

12 A. (Witness reviews document.) I'm sorry.
13 Could you repeat the question.

14 **Q. Yeah.**

15 MR. SABER: Could you read it back,
16 please.

17 (Question read back.)

18 MR. BONELLA: Object to form.

19 **Q. Let me rephrase that. Does that paragraph
20 provide suggested polymers to provide improved
21 strength to the braid?**

22 MR. BONELLA: Object to form.

23 A. That paragraph describes two sets of --
24 that describes "Lubricating yarns in the first
25 set --"

1 MR. BONELLA: Object to form.

2 A. Those --

3 **Q. As providing the strength.**

4 A. Those are the only --

5 MR. BONELLA: Object to form.

6 A. -- ones mentioned.

7 **Q. In that paragraph?**

8 A. As far -- yes.

9 **Q. Is there any other mention in this patent
10 -- specific mention of any other yarn there to
11 provide strength?**

12 MR. BONELLA: In the patent?

13 MR. SABER: Yes, sir.

14 MR. BONELLA: If he needs to read the
15 patent, read the entire patent to answer the
16 question then.

17 A. Are there any other fibers mentioned --

18 **Q. Any other yarns mentioned to provide
19 strength --**

20 A. I would say.

21 **Q. -- to the --**

22 A. Any of the polymers that we mentioned
23 could be the strength.

24 **Q. Could you tell me where it says that. I
25 want to know exactly what you're relying upon in**

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1 A. That's a sheathe and core on fiber level.
2 **Q. Okay. On the fiber --**
3 A. And that's -- and that can be braided into
4 -- so you could have -- what I was trying to show
5 there is you could have a co-extrusion, if you
6 will, of two different polymers.
7 **Q. Could you explain to me what you're**
8 **talking about there.**
9 A. Yeah. You could have a construction where
10 each individual filament of each individual yarn
11 essentially had more than one polymer type.
12 **Q. Okay.**
13 A. So, you're blending at a level -- as you
14 go down this list, it's a more intimate blend of
15 fiber types.
16 **Q. Okay. Well -- maybe it's best to talk**
17 **each separately. Did you consider using a carrier**
18 **blend where Spectra would be one of the yarns and**
19 **something else would be the second yarn?**
20 A. I considered using high-tenacity fibers,
21 including Spectra for any of the top three --
22 **Q. Okay.**
23 A. -- carrier yarn or fiber commingled.
24 **Q. Okay.**
25 A. And that would be Spectra, Kevlar, any of

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1 the high tenacity ones, that was part of the
2 generic concept of, can you manipulate the
3 mechanical properties?
4 **Q. Okay. Did you -- is there any**
5 **documentation that you know of using Spectra as one**
6 **of the yarns in any of the first three processes**
7 **described here?**
8 A. I suspect that it was documented, but I --
9 I'm not familiar with where and in whose
10 notebook --
11 **Q. Would you expect it to be in someone's**
12 **notebook?**
13 A. I know we were poking around that area. I
14 would suspect it was captured. Unfortunately,
15 that's a big group and a long time ago.
16 **Q. Do you know whether any -- any prototypes**
17 **were built under any of these three types of --**
18 **these three processes where Spectra was one of the**
19 **yarns with a second dissimilar -- second different**
20 **yarn?**
21 A. I would -- most likely not. We were
22 trying to demonstrate the concept, and we -- we
23 didn't feel we needed to do that on a lot of
24 different fiber types, and Spectra was one of the
25 more difficult ones to process.

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1 **Q. That's a you don't think you did it? Is**
2 **that your answer?**
3 A. Yeah, I don't think we did it.
4 **Q. Okay. Do you have -- did you think of --**
5 **did you --**
6 A. And by the -- oh. Can I clarify one
7 thing? When I say, "Spectra," there were multiple
8 sources of that, and I may not just be -- it might
9 not have just been the Allied. There was one from
10 Holland as well.
11 **Q. Called Dyneema?**
12 A. Yes.
13 **Q. And when you say, "Spectra," if I were to**
14 **substitute Dyneema, Spectra or Dyneema --**
15 A. Yes. Yeah.
16 **Q. -- that would be a fair thing?**
17 A. Yes.
18 **Q. Did you have an idea of which yarn you --**
19 **to braid Dyneema with?**
20 A. Which yarn would we have braided it with?
21 **Q. Yes, sir. Did you have that idea?**
22 MR. BONELLA: Objection. Asked and
23 answered.
24 A. Generically, one which would improve the
25 knot strength of Dyneema.

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1 **Q. Would that include PET?**
2 A. It would include, essentially, all of the
3 current -- all of Ethicon's non-absorbable
4 multifilaments at the time, which would include
5 PET, nylon, silk -- that's it.
6 **Q. So, if I understand your testimony --**
7 A. Yes.
8 **Q. -- you had, at least in your mind --**
9 A. Yes.
10 **Q. -- the idea of braiding together Dyneema**
11 **and PET.**
12 A. It was one of the combinations, yes.
13 **Q. And did you have a view -- and when did**
14 **you have this idea?**
15 A. This -- this would date back to the early
16 conversation with Al Hunter in terms of what
17 benefits could we derive from forming composites of
18 dissimilar fibers.
19 **Q. Did you have -- in formulating this idea,**
20 **did you have any sort of belief that if you put**
21 **Dyneema together with PET, it would lead to an**
22 **acceptable suture?**
23 A. It would lead to a suture with potentially
24 improved properties over Ethibond.
25 **Q. Did you have a belief as to whether that**

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1 **would be an acceptable suture?**
2 MR. BONELLA: Objection. Asked and
3 answered.
4 A. We had a belief that it could lead to --
5 as you're saying -- an acceptable suture. There
6 were other issues that we didn't know. For
7 example, how the -- how polyethylene behaved in the
8 body. So, it was a high priority. Polyethylene,
9 even though there was an interest, it wasn't a --
10 it wasn't something that was a high priority at the
11 time.
12 **Q. The thought didn't cross your mind that,**
13 **Oh, this would make an unacceptable suture to put**
14 **Dyneema together with PET?**
15 A. My recollection was -- an unacceptable
16 suture or an acceptable?
17 **Q. An unacceptable suture.**
18 A. Well, the concern with any of the very
19 high-strength fibers was always knot strength, and
20 that was true whether it was Dyneema, Spectra,
21 Kevlar, etcetera. So, the general view was, I
22 mean, all of those -- 100 percent, all of those,
23 Ethicon evaluated at one point as a suture
24 material. They're the world's biggest suture
25 material company. And all of them there was an

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1 interest in how do you improve the knot strength of
2 them, and can you -- that was -- that was something
3 we discussed.
4 **Q. I'm not sure I understand your answer.**
5 A. Go ahead.
6 **Q. And I'm trying to --**
7 A. Sure.
8 **Q. When you had this idea that you could**
9 **blend Dyneema together with PET, were you -- did**
10 **you believe it would make an acceptable suture or**
11 **an unacceptable suture?**
12 A. No. We believed -- we believed that that
13 could offer a suture with straight tensile that was
14 better than Ethibond, and you know, could
15 potentially solve the knot issues, and again, that
16 was a generic view for all of the high-tenacity
17 fibers.
18 **Q. You thought it was a good idea --**
19 A. Yes. Yes.
20 **Q. -- rather than a bad idea?**
21 A. No, we viewed -- we viewed that as a
22 potential good idea.
23 **Q. And you didn't think, Oh, that's a bad**
24 **idea.**
25 MR. BONELLA: Objection. Asked and

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1 answered.
2 A. I don't know if it was good or bad. You
3 know, it was --
4 **Q. You thought it was a good idea?**
5 A. We thought we could have improved knot
6 strength, and we could get the beneficial
7 properties of both in a blend. That's what we
8 thought.
9 **Q. Okay. Is there any documentation of using**
10 **Dyneema or Spectra, blending it together with**
11 **another component -- another -- a yarn -- is there**
12 **any documentation that exists that you know of?**
13 A. I haven't -- I haven't seen any. I am not
14 aware of any.
15 **Q. Do you know whether that was in your idea**
16 **memo?**
17 A. I do not know. I have not seen my idea
18 memo.
19 MR. BONELLA: He said he doesn't know if
20 he did.
21 THE WITNESS: I'm sorry.
22 MR. SABER: Actually, he did. He
23 testified he does remember doing it, but that's
24 okay.
25 **Q. Could you look at the Claim 1 of the 446**

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1 **patent, please. And I want to talk about Group A**
2 **and the Group B.**
3 A. Okay.
4 **Q. Other than PET and PP or PET and PTFE, is**
5 **there any documentation that you know of that**
6 **exists of any other combination of one yarn from**
7 **the first group and one yarn from the second group?**
8 MR. BONELLA: Object to the form of the
9 question.
10 A. The only documentation that I can speak
11 with any confidence is -- is this. I mean, it's
12 just been too long.
13 **Q. I'm just asking you to do the best you**
14 **can.**
15 A. Yeah, of course. So, I mean, I can't
16 speak with any confidence that there's
17 documentation that shows any other combination.
18 **Q. Do you --**
19 A. My recollection was --
20 **Q. Go ahead.**
21 A. -- to show the concept we focused on PET
22 and PTFE, and PET and polypropylene. We thought
23 that it would demonstrate the concept. Some of
24 these materials, as you may know, are not readily
25 available in the form that we would need. You

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